

Global Treatment Access: Legal Developments and Strategies

Papers prepared for:

Putting Third First: Vaccines, Access to Treatment & the Law

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Global Treatment Access: Legal Developments and Strategies

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ACCESS TO TREATMENT IN DEVELOPING COUNTRIES: QUESTIONS FOR DISCUSSION AT SATELLITE WORKSHOPS

We ask that participants in the treatment access workshops at the satellite meeting read the attached background papers before the meeting. While you read the materials, consider the following questions, which it is intended will be discussed in the workshops at the meeting.

1. International advocacy for treatment access in developing countries

Which avenues and tactics should treatment activists use at the international level to advance access to treatment for people living with HIV/AIDS?

What could be done in forums or through mechanisms focussed on the following areas:

- human rights?
- global health?
- international trade?
- global finance and development?

Are there issues or areas that should clearly be the most important priorities for treatment activists, and what avenues or tactics should be used in those areas?

2. National advocacy for treatment access in developing countries

Participants from *developing* countries:

- What are the most important barriers to access to treatment for people living with HIV/AIDS in your country?
- How could you undertake or expand effective action to remove those barriers?
- What role can legal analysis, law reform or litigation play in those efforts?
- What action could be undertaken in the next year? How and by whom?

Participants from *developed* countries:

- What is the current ability of you and your allies to undertake effective advocacy for access to treatment in developing countries?
- What do you need to become (more) active or effective as an activist for access to treatment in developing countries?
- What action could be undertaken in the next year? How and by whom?

3. Collaboration with vaccine advocates

How can vaccine advocates and treatment advocates work together to advance our mutual interests in realizing the right to health of people living with or vulnerable to HIV/AIDS?

EXECUTIVE SUMMARY

The 2000 International AIDS Conference focussed worldwide attention in a new way on the desperate scale of the HIV/AIDS pandemic in developing countries (particularly Africa). Front and centre was the "iniquity of very considerable proportions"¹ that few of the millions of individuals and families living with (and dying from) the disease have access to medicines that are cheap to produce and can extend or save lives, while the technology and the resources to intervene to prevent untold human suffering and socio-economic degradation are held by the world's richest. What that gathering highlighted was the absence of moral concern, political will, and financial commitment on the part of the powerful; what it catalysed was a growing activist movement that seeks to generate that concern, that will, those resources. Thanks to the domestic and international work of those activists — from demonstrations to court cases, from acts of public courage by individual people living with HIV/AIDS to ongoing lobbying of politicians and trade negotiators — some very significant developments have occurred. But the reality remains that the vast majority of people living with HIV/AIDS still lack access to affordable, quality medicines.

This satellite, "Putting Third First", aims to contribute to one aspect of the movement. The objective is to identify and discuss strategies for using the law—as one tool among, and in conjunction with, other tools—to advance access to medicines for people living with HIV/AIDS in developing countries. Discussion among community organizers, lawyers and others will provide an opportunity for activists from different countries and regions to learn from each other's experiences working for improved access to treatment using various legal (and non-legal) strategies. The meeting aims to:

- increase participants' understanding of the barriers to access to treatment in developing countries and of the possible role of law in creating or removing those barriers;
- enhance participants' commitment to advocacy on some of the legal dimensions of the barriers to treatment access at national, regional and international levels; and
- identify means for ongoing collaboration between participants to implement strategies identified.

To this end, and recognizing that participants will come from very different contexts with varying levels of knowledge and experience about legal issues related to treatment access, the attached materials have been prepared to facilitate the workshop discussions at the meeting.

Law and access to treatment

The organizers of the meeting are committed to the proposition that human rights are central to our collective response to the global HIV/AIDS pandemic, and that activists must therefore critically engage with the law — to challenge and change it where it is part of the problem, to pursue enforcement and respect for it where it is part of the solution, and to use it strategically where possible and necessary to advance the rights of people living with HIV/AIDS and those vulnerable to both the virus and human rights abuses.

¹ Mr. Justice Edwin Cameron. The Deafening Silence of AIDS. Jonathan Mann Memorial Lecture, 13th International AIDS Conference, Durban, 10 July 2000, reproduced at: *Canadian HIV/AIDS Policy and Law Review* 200; 5(4): 79-86.

International and domestic law set the rules governing the production, approval, sale and purchase of medicines, with an obvious impact on the accessibility of medicines to those who need them. Where the law creates barriers to treatment access (e.g., overly strict patent laws supporting high prices for drugs under patent), activists must necessarily engage in legal analysis and advocacy for law reform. The law may also be used to increase access to treatment as a government policy objective (eg, directly regulating the price of medicines, setting price conditions for bulk purchasing, etc). Legal mechanisms may be used to confront the conduct of private corporations that impedes access to medicines (e.g., challenging price gouging on pharmaceutical products) or to hold governments accountable for their inaction (e.g., redressing discriminatory refusals to cover anti-retrovirals under public health insurance schemes, compelling action to provide medicines).

As background, preparatory reading for the satellite, a very brief chronological overview of some recent key legal and policy developments related to treatment access is presented below. In addition, the three attached papers have been prepared, looking at the issue of "law, human rights and access to medicines" from three different angles.

(1) Advancing human rights law: the right to health and access to medicines

The first paper, *Access to Treatment and the Human Right to Health: Recent Developments and Future Strategies*, was contributed by the Canadian HIV/AIDS Legal Network. Its goal is to consider ways in which the recognition and promotion of a right to health in human rights law can be pursued.

First, the paper provides a descriptive overview of the state of "right to health" in international human rights law. It outlines the basis in international and regional human rights law for a right that is, at least theoretically, legally "enforceable" (subject to the well-known difficulties of enforcing international human rights norms), and the possible content of that right. It summarizes some important recent developments relating specifically to the issue of access to medicines as part of that right, including the potential significance of the World Trade Organization's "Doha Declaration" on its international trade agreement on patents and countries' freedom to take measures to improve access to medicines.

Second, it provides a summary of the experience to date in litigating claims to the right to health using international mechanisms (eg, the Inter-American Commission on Human Rights) and before national tribunals (eg, court victories in South Africa and numerous Latin American countries ordering government payment for HIV/AIDS drugs).

Finally, it identifies some areas in which treatment access advocates can advance and consolidate recognition of the right to health in human rights law (international and domestic). Some activities are more feasible, others would require greater resources and be more controversial. Possibilities include:

General advocacy in the UN system:

- input into the work of the newly-appointed Special Rapporteur on the right to health and the existing rapporteurs with related mandates (eg, on globalization and its impact on economic, social & cultural rights);

- submitting NGO "shadow" reports focussing in access to medication and other aspects of health care to expert committees responsible for reviewing periodic country reports under a variety of treaties (on economic, social & cultural rights; on discrimination against women or racial discrimination; on the rights of children; on civil & political rights), which could be undertaken by activists in both developing and developed countries to focus on both domestic and international efforts to realize access to treatment. This could also be done in the Inter-American, African and European human rights systems under regional treaties;
- making submissions to the UN Committee on Economic, Social & Cultural Rights and otherwise inputting into its process of preparing a General Comment on intellectual property and human rights;
- working with government delegations in a body such as the UN Commission on Human Rights to adopt further resolutions solidifying in international law the right to access medicines, particularly in the event of further significant developments in other areas (eg, WTO law);

Litigating using international mechanisms

- in those countries which have ratified the Optional Protocols to the Conventions on discrimination against women and on civil & political rights, filing communications with the Committee identifying breaches of women's right to health under CEDAW or the right to life and freedom from cruel, inhuman or degrading treatment under ICCPR;
- lodge petitions with the Inter-American Human Rights Commission alleging that denial of access to medication is in violation of instruments in that regional system;
- file "communications" with the African Commission on Human and People's Rights identifying the lack of government action to improve access to medications as a "serious and massive violation" of the right to health set out in the *African Charter of Human and People's Rights*;

Domestic lobbying, advocacy, human rights education

- lobby governments for follow-up action on such things as the UN General Assembly's Declaration of Commitment on HIV/AIDS or the resolutions of the UN Commission on Human Rights calling on states to report on measures taken to increase access to medication;
- undertake a "human rights audit" of national legislation relevant to treatment access for the purposes of informing a domestic advocacy agenda
- prepare a document articulating the key points of that treatment access agenda and use it to engage government, legislators, the public and media;
- organize workshops and public education sessions on the right to health and access to medicines and to promote an articulated advocacy agenda and engage potential allies, as well as specific workshops devoted to building knowledge and skills of a core group of treatment access activists;
- prepare materials for media to set out goals of advocacy agenda and promote informed, pro-human rights coverage of the issue of access to treatment;

Domestic litigation

- identify legal proceedings that could be initiated by NGOs, or in which NGOs could intervene, to advance human rights-based arguments for access to treatment and could lend themselves to other, complementary advocacy activities and opportunities for media coverage to shape public opinion.

Identifying specific cases or strategies in this area is difficult, given widely differing legal and political systems.

(2) Controlling the price of medicines and cost to purchasers

The second paper, *Drug Financing and Price Control: Legislative Intervention in the Public Interest*, was contributed by the Lawyers Collective HIV/AIDS Unit in India. It seeks to make more understandable the ways in which governments can intervene in the market to make medicines more affordable, both through directly controlling drug prices ("supply-side" mechanisms) and through financing the purchase of drugs ("demand-side" mechanisms).

The paper identifies that most developed countries use one or both of these kinds of interventions to advance the public interest in wider, more affordable access to medicines. Yet, while this need is even greater in developing countries, most have not adopted any such coordinated strategy. Therefore, it is important for treatment access activists to become active in this area.

The paper describes both demand-side and supply-side mechanisms for increasing affordability of medicines, to both individual consumers and to government when it acts as public insurer paying for some or all of these costs.

- Supply-side mechanisms target identifiable aspects of the supply of drugs by manufacturers, such as prices, profits or costs.
- Demand-side mechanisms target the consumers of products, usually through public health insurance programs which reimburse or subsidize prices.

The paper then provides a snapshot of approaches in several developed countries that use these mechanisms, more or less robustly, with correspondingly greater or lesser effect on the affordability of medicines. The paper identifies the various international and domestic pressures influencing government policy on these fronts (political considerations, trade law, market forces, the tension between controlling prices and the claim of jeopardizing private research & development into new medicines).

With this in mind, the paper outlines some potential issues concerning the use of these regulatory mechanisms by developing countries, noting that current initiatives to implement equitable pricing policies in developing countries should not include wholesale adoptions of legislative models from industrialized countries. Nonetheless, the legislative pricing frameworks adopted by developing countries will *also* be the outcome of balancing competing interests.

In reality, limited public funds means that public financing of drugs alone cannot comprehensively ensure drug accessibility and affordability. Therefore, supply-side mechanisms to control prices are necessary, such as direct capping of prices, encouraging generic competition (including through the use of measures permitted under the WTO TRIPS Agreement on patents), and differential pricing policies.

The paper uses the experience of price controls in India as a case study of how international and domestic pressures have led, and continue to lead, to an ongoing weakening of government action in this area, to the detriment of access to medicines. The paper notes that the WTO's TRIPS Agreement does not restrict WTO member nations from imposing price control on pharmaceutical products, meaning this is a legal tool open to countries to make medicines more accessible. But in the case of India, the Drug Price Control Order envisages price control of drugs manufactured in India only. If the TRIPS Agreement is

interpreted as prohibiting countries from requiring that a patent holder ‘work’ a patent (ie, make the patented drug) locally in order to obtain patent rights in a country, then importation of drugs produced elsewhere is more likely. Not only does this undermine the development of a country's national technical capacity to produce medicines, it could also mean that patent-holding companies abroad will sell their drugs in India without being subject to price control locally – because of TRIPS and since criteria under DPCO are insufficient to cover overseas manufacturers. This points to an important area for law reform advocacy by treatment access activists.

The paper concludes by drawing various lessons from the experience of developed countries, such as the likely need for both price controls and comprehensive drug financing systems to achieve greatest affordability, but this requires a more developed regulatory infrastructure to implement. It notes this will likely be the case for developing countries as well, but that sustainable financing will often be difficult, and that technical assistance for developing the necessary regulatory infrastructure could be sought from the World Health Organization and through regional sharing of information.

It also concludes that individual country negotiations for drug discounts take time and may come with onerous conditions; legislated automatic pricing mechanisms can better address immediate health needs without compromising country autonomy. Furthermore, legislation should impose direct price controls on all products sold within a country, regardless of manufacturing origin.

(3) Litigating for medicines

The third paper, *Litigation Strategies to Gain Access to Treatment: The Case of South Africa's Treatment Action Campaign*, was contributed by the AIDS Law Project in South Africa.

The paper describes the commitment of the grassroots Treatment Action Campaign (TAC) to using litigation not only to seek legal vindication and enforcement of people's constitutional and human right to access health care (including medicines) but also as part of a broader process of social mobilization. In addition, by framing political and moral demands in the language of legal rights and constitutional obligations, TAC seeks to use the law without necessarily having to litigate, by bringing laws and decisions under human rights scrutiny and placing issues on the agenda of both judges and the court of public opinion. It notes that TAC succeeded in turning the much-publicized case of pharmaceutical company litigation against the South African government into both a legal case about human lives (rather than just intellectual property rights) and an opportunity for shaping public opinion.

The paper then discusses three areas in which TAC is using or contemplating litigation to improve access to medicines:

- TAC has succeeded in December 2001 in obtaining an initial court order that, in order to prevent mother-to-child transmission (MTCT) of HIV, the government must (1) supply the anti-retroviral drug nevirapine to HIV-positive pregnant women where public health facilities have the capacity to do so and (2) plan and implement a phased rollout of a comprehensive national program to prevent MTCT. That decision and the public pressured mobilized by TAC and others has led to movement by various provincial governments, and even the national government, although the decision is currently under appeal to the country's Constitutional Court. At issue is the extent to which a court may review policy

decisions of the state; the outcome will have a significant ripple effect on both domestic and international efforts to legally enforce the right to health and other social and economic rights through court action.

- TAC is also preparing its intervention in an existing complaint to the South African Competition Commission in which a generic company (a joint South African/Indian venture) is alleging that certain brand-name pharmaceutical companies have abused their dominance in the market by engaging in excessive pricing of their products and entering into certain exclusionary licensing and/or agency arrangements. TAC will seek to ensure that South Africa's competition law is used to grant compulsory licenses to ease the entry of generic anti-retrovirals (specifically AZT, 3TC, nevirapine, and an AZT/3TC combination) onto the market, bringing down prices. TAC will again coordinate public campaigning to complement the legal process.
- Finally, TAC is contemplating legal action to challenge the limitation on benefits provided to people living with HIV/AIDS by one of the country's largest private health care insurers. It will likely focus on cases in which treatment has been interrupted during hospitalisation because the private insurer's limits force the person to "choose" between having to pay the high costs of hospitalisation out of pocket or relocate to a public health facility.

INTRODUCTION

Access to treatment was a defining theme of the 13th International AIDS Conference in Durban in 2000, and the *Putting Third First* satellite held then. The issue attracted world attention and catalyzed efforts by communities, activists and policy-makers to address a global crisis. Since then, numerous developments have occurred as a result of sustained activism – some positive, some negative, some whose impact is yet to be fully determined.

These developments range from resolutions adopted at the United Nations on access to medication as a human right to the successful mobilization by treatment activists in South African litigation over pharmaceutical legislation; from the adoption of a WTO Ministerial Declaration on the TRIPS Agreement and Public Health to significant price reductions on some medicines; from the establishment of a Global Fund to Fight AIDS, TB and Malaria (which remains drastically under-funded) to significant court judgments in Venezuela and South Africa compelling government to make anti-retroviral medicines available.

But the barriers to global treatment access are complex. Multiple challenges remain in realizing the simple proposition that, as a matter of basic human rights, people should have equitable access to those goods and services needed to protect and maintain health. In defending and advancing this right, regard must necessarily be had to the law as one dimension.

International and domestic law set the rules governing the production, approval, sale and purchase of medicines, with an obvious impact on the accessibility of medicines to those who need them. Where the law creates barriers to treatment access (e.g., overly strict patent laws supporting high prices for drugs under patent), activists must necessarily engage in legal analysis and advocacy for law reform. The law may also be used to increase access to treatment as a government policy objective (eg, directly regulating the price of medicines, setting price conditions for bulk purchasing, etc). Legal mechanisms may be used to confront the conduct of private corporations that impedes access to medicines (e.g., challenging price gouging on pharmaceutical products) or to hold governments accountable for their inaction (e.g., redressing discriminatory refusals to cover anti-retrovirals under public health insurance schemes, compelling action to provide medicines).

Goals of the satellite meeting

As the name of the satellite meeting suggests, the discussion will focus on ways to advance the human rights of those infected, affected and most vulnerable to HIV/AIDS in the developing world, with a particular focus on legal issues and strategies.

The objective of the "access to treatment" stream of the satellite meeting is to identify, and stimulate discussion of, strategies for using the law to advance access to treatment for people living with HIV/AIDS in developing countries. To this end, the enclosed background documents have been prepared and distributed to participants. These papers provide a basis for a facilitated discussion among community activists, lawyers and others, providing an opportunity for participants from different countries and regions to learn from each other's experiences working for improved access to treatment using various legal (and non-legal) strategies. The meeting and the documents produced aim to:

- increase participants' understanding of the barriers to access to treatment in developing countries and of the possible role of law in creating or removing those barriers;
- enhance participants' commitment to advocacy on some of the legal dimensions of the barriers to treatment access at national, regional and international levels; and
- identify means for ongoing collaboration between participants to implement strategies identified.

To this end, three short papers have been prepared. Each examines some specific developments in, or uses of, the law as a vehicle for improving access to medicines for people living with HIV/AIDS as a critical part of advancing the right to health. Each paper has a different focus:

- The first paper looks at developments in gaining legal recognition of access to medicines as part of the human right to health, in both international law and in the domestic law of various countries. It identifies possible opportunities to advance the right to health generally and access to medicines as a specific element of that human right.
- The second paper examines legal mechanisms for controlling the prices of medicines to make them more affordable for purchasers, be they individual patients or group purchasers such as the state's public health insurance schemes. It draws upon the experience in many developed countries of government intervention in the pharmaceutical market and presents ideas for policy in developing countries. It presents a case study of drug price controls in India as one example.
- The third paper presents a case study from South Africa. It discusses the experience of the Treatment Action Campaign, a grassroots treatment activism organization, in using the courts to advance human rights claims for access to HIV/AIDS treatment, and contemplates three other areas in which litigation could be used as a strategy.

Following the satellite meeting, a final document incorporating the key points from the background papers and satellite discussion will be prepared, providing participants and others interested in global treatment access with a useful tool for informing their own ongoing national, regional and international efforts following the conference.

GLOBAL TREATMENT ACCESS: AN OVERVIEW OF RECENT LEGAL & POLICY DEVELOPMENTS

The following provides a short chronological review of some key developments in law and policy relevant to increasing access to treatment for people living with HIV/AIDS in developing countries. (Numerous other developments, such as drug price reductions by corporations, launching of various initiatives, etc are not mentioned here.)

2000

May

US President Clinton issues executive order pledging the US will not oppose efforts by African countries to take TRIPS-compliant measures aimed at increasing access to HIV/AIDS drugs

July

- UN Committee on Economic, Social & Cultural Rights releases General Comment No. 14 on the right to health
- 13th International AIDS Conference in Durban, South Africa focuses world attention on the HIV/AIDS crisis in developing countries (specifically in Africa) and the issue of lack of access to medicines

August

- GSK threatens legal action against Cipla if it pursued its offer to sell a generic 3TC/AZT dual combination (Duovir) in Ghana; it was later revealed that GSK had no valid patent on the drugs in Ghana

December

- Indian generic manufacturer CIPLA offers to pay 5% royalties to Bristol-Myers Squibb, Pfizer, Boeringer-Ingelheim & GlaxoSmithKline in exchange for a voluntary license to sell generic version of patented anti-retrovirals in developing countries

2001

April

- Pharmaceutical Manufacturers Association of South Africa abandons suit against South African government challenging constitutionality of legislative measures that could be used to increase domestic access to medicines
- UN Commission on Human Rights adopts resolution recognizing access to medication in the context of pandemics such as HIV/AIDS as a human right
- African heads of state adopt Abuja Declaration & UN Secretary General calls for establishment of a global fund to fight AIDS of US\$7-10 billion *per year*

June

- Kenya enacts new Intellectual Property Bill that only includes some measures to promote access to affordable medicines, fails to include provisions for compulsory licensing
- UN General Assembly adopts *Declaration of Commitment on HIV/AIDS*
- Global Fund to Fight AIDS, TB & Malaria established
- Brazil and US settle complaint brought by US alleging Brazil's "local working" requirements for enjoyment of full patent rights are non-compliant with WTO TRIPS Agreement

November

- 4th WTO Ministerial Conference (Doha, Qatar) adopts Declaration on the TRIPS Agreement and Public Health

- UN Committee on Economic, Social & Cultural Rights issues statement on "Intellectual Property & Human Rights", as preliminary step to preparing a General Comment on the issue

December

- Pretoria High Court (South Africa) orders South African government to provide pregnant women with access to nevirapine where testing and counselling capacity exists and to plan and progressively implement an effective comprehensive national programme to prevent or reduce mother-to-child HIV transmission

2002

January

- Global Fund to Fight AIDS, TB& Malaria becomes operational (as of July 2002, Fund has *total* commitments of US\$2 billion, several pledges being spread over multiple years)
- NGOs propose option to WTO Council for TRIPS to overcome limits under TRIPS Agreement Article 31(f) on export of generic medicines produced under compulsory license²

March

- WTO Council for TRIPS meeting (1st meeting after Doha Declaration): proposals submitted by developing countries to address problem of limits on export of generic drugs produced under compulsory license; industrialized countries push for restrictions on any agreement³
- World Health Organization (WHO) includes 11 anti-retroviral medications (ARVs) and 5 medicines for the treatment of opportunistic infections on in its list of essential medicines

April

- UN Commission on Human Rights adopts resolution on access to medication in the context of pandemics such as HIV/AIDS
- UN Commission on Human Rights adopts resolution to appoint a Special Rapporteur on the right to health

May

- Zimbabwe declares a 6-month period of emergency to facilitate the issuing of compulsory licenses on anti-retrovirals

June

- WTO Council for TRIPS meeting (2nd meeting after Doha Declaration): ongoing negotiations regarding issue of TRIPS Agreement Article 31(f) limits on export of generic medicines produced under compulsory license

² Letter from Consumer Project on Technology, Essential Action, Médecins Sans Frontières, Oxfam International, Health GAP Coalition, & Third World Network to the World Trade Organization's TRIPS Council, 28 January 2002, available at: <http://www.cptech.org/ip/health/art30exports.html>.

³ See proposals on WTO website at: http://www.wto.org/english/tratop_e/trips_e/trips_e.htm.

PAPER #1

ACCESS TO TREATMENT AND THE HUMAN RIGHT TO HEALTH: RECENT DEVELOPMENTS AND FUTURE STRATEGIES

RICHARD ELLIOTT*

People no longer accept that the sick and dying, simply because they are poor, should be denied drugs which have transformed the lives of others who are better off.⁴

I. INTRODUCTION

It is often observed that human rights, and in particular economic and social rights, presently enjoy much greater currency as idealistic norms or aspirations than as realistically enforceable legal entitlements. Certainly the enforcement of such rights, and particularly those standards found in international law, is an uphill struggle. But it would be facile to conclude, therefore, that this body of norms and of law is worthless, to be ignored by activists concerned with effecting real, concrete change such as securing access to needed medicines for people living with HIV/AIDS. To do so would be to give up on one (admittedly imperfect) tool that can occasionally be successfully applied, in conjunction with other measures, to this most urgent project. This human rights activists cannot afford to do,⁵ particularly not at a point when much hard effort is finally yielding some long-sought developments in the recognition of the human right to health.

Human rights norms as stated in international and domestic law have an important symbolic value — as precepts which governments themselves have recognized, thereby giving them some rhetorical weight in efforts to shape public policy, and as moral claims that can inspire and empower individuals and communities, helping to "imbue a sense of popular ownership of governance and development" and to "legitimize claims or agitations for their provision."⁶ They also have a more tangible legal value — they can, given the right configuration of political will, public opinion, and/or judicial resolve, be legally enforced, generating real benefit for real people. As one commentator points out:

Possibilities of claiming economic, social and cultural rights internationally or regionally and thus, in theory, redressing violations of these rights, must not be viewed as an act of ultimate futility. Reliance on human rights law has stopped planned violations from occurring and has, in some

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⁴ Kofi Annan, UN Secretary General. News release: "Secretary-General proposes global fund for the fight against HIV/AIDS and other infectious diseases at African leaders summit," SG/SM/7779/Rev.1, 26 April 2001.

⁵ Others have stressed the importance of activist engagement with the law. See, for example: Alicia Ely Yamin. "Protecting and Promoting the Right to Health in Latin America: Selected Experiences from the Field." *Health & Human Rights: An International Journal* 2000; 5(1).

⁶ Felix Morka, Social and Economic Rights Action Centre (Nigeria). "Combating Poverty Through the International Human Rights Framework" (undated, available at: www.frontlinedefenders.org/en/papersweb/p8en.doc).

cases, provided relief to victims. The effectiveness of the remedial procedures which do exist, the frequency of their use, the seriousness accorded them by States, the range of coverage and the degree to which any decisions stemming from them actually alter local circumstances, however, remain limited.⁷

The daunting challenge is to collectively identify opportunities and strategies for advancing the recognition and enforcement of such rights. This paper seeks to stimulate some discussion to that end, with a particular focus on advancing the right to health and, more specifically, the access of people living with HIV/AIDS to needed treatment. It first outlines the nature and scope of the right to health in international law, then considers the specific issue of access to medicines as part of that right. It provides an overview of litigation experiences seeking to enforce access to medicines as a human rights claim. Finally, it identifies for discussion some possible strategies for advancing the legal rights of people living with HIV/AIDS to access medicines.

II. THE HUMAN RIGHT TO HEALTH: INTERNATIONAL LAW⁸

The "enjoyment of the highest attainable standard of health" has been recognized as "one of the fundamental rights of every human being" by the international community since the adoption of the *Constitution of the World Health Organization* in 1945,⁹ followed shortly thereafter by the adoption of the UN Charter.

The *Charter of the United Nations*¹⁰ makes no specific reference to a right to health, but nonetheless imposes a treaty obligation on UN member states to "take action" to realize the right to health. Under the UN Charter, member states "pledge themselves to take joint and separate action" for the achievement of, among other things: "higher standards of living... and conditions of economic and social progress and development"; "solutions of international...health problems"; and "universal respect for, and observance of, human rights and fundamental freedoms for all".¹¹ Furthermore, countries' obligations under the UN Charter supersede those under other international agreements in the event of a conflict.¹²

⁷ Scott Leckie. "Violations of Economic, Social and Cultural Rights." In TC van Boven, C Flinterman & I Westendorp (eds). *The Maastricht Guidelines on Violations of Economic, Social and Cultural Rights — SIM Special No. 20*. Utrecht: SIM, 1998 (available at: www.law.uu.nl/english/sim/specials/simsp20.asp).

⁸ For a more in-depth discussion of the human right to health in international law, see: Brigit CA Toebe. *The Right to Health as a Human Right in International Law*. Antwerp: Intersentia-Hart, 1999; Audrey R Chapman. "Violations of the Right to Health." *SIM Special No. 20: The Maastricht Guidelines on Violations of Economic, Social & Cultural Rights*, 1998 (available at: www.law.uu.nl/english/sim/specials/simsp20.asp); Audrey R Chapman. "Conceptualizing the Right to Health: A Violations Approach". *Tennessee Law Review* 1998; 65: 389; Virginia A Leary. "The Right to Health in International Human Rights Law." *Health & Human Rights* 1994; 1(1) (available in full on-line at: <http://www.hsph.harvard.edu/fxbcenter/V1N1leary.htm>); R Bachand & L Lamarche. "Le droit à la santé et la lutte contre la pauvreté en Afrique." Centre d'études sur le droit international et la mondialisation (CEDIM), Université du Québec à Montréal, 2000 (available via: www.cedim.uqam.ca).

⁹ 14 UNTS 185. The Constitution of the WHO was adopted by the International Health Conference, New York, 19-22 June 1945; opened for signature on 22 July 1946 by the representatives of 61 States; and entered into force on 7 April 1948.

¹⁰ Charter of the United Nations, 26 June 1945 (entered into force 24 October 1945), TS 67 (1946).

¹¹ UN Charter, Articles 55 and 56.

¹² UN Charter, Article 103.

In the 1969 *Vienna Convention on the Law of Treaties* (VCLT), states recognized "universal respect for, and observance of, human rights and fundamental freedoms" as "principles of international law embodied in the Charter of the United Nations."¹³ The VCLT also confirmed, as a matter of law, that every treaty (such as the UN Charter and subsequent human rights treaties) in force "is binding upon the parties to it and must be performed by them in good faith."¹⁴

The content of those rights, and the nature of states' obligations in realizing them, is set out elsewhere in international law, both customary and conventional (also known as "treaty law"). With respect to the customary international law,¹⁵ the *Universal Declaration of Human Rights* (UDHR) states that "everyone has a right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, and medical care and necessary social services."¹⁶ It also provides that "everyone has the right... to share in scientific advancement and its benefits."¹⁷

As a declaration of the UN General Assembly, the UDHR is not a legally binding treaty. However, it is generally accepted that the UDHR (or at least many of its provisions) has attained the status of *customary international law* - namely, those general practices recognized by States, with substantial uniformity, as being required by prevailing international law. As such, it is legally binding upon all the world's States, including those that did not approve it at the time of its adoption in 1948.¹⁸ This conclusion is bolstered by the fact that the world's states have repeatedly re-affirmed the obligation to implement the UDHR. For example, the declaration adopted by 171 States at the UN's World Conference on Human Rights in 1993 reaffirmed States' human rights obligations in accordance with the UN Charter and the UDHR, and declared that the "protection and promotion [of human rights] is the first responsibility of Governments."¹⁹ This also lends further strength to efforts to enforce claims under the various human rights treaties.

The rights articulated in the UDHR are elaborated in more detail in various treaties subsequently adopted. In particular, the 152 States that are parties to the *International Covenant on Economic, Social and Cultural Rights* "recognize the right of everyone to the enjoyment of the highest attainable standard of

¹³ Preamble, *Vienna Convention on the Law of Treaties* (1969), 1155 UNTS 331.

¹⁴ VCLT, Article 26 (the principle of *pact sunt servanda*). The International Court of Justice has recognized States' obligations under the UN Charter as legally binding: *Namibia Advisory Opinion*, [1970] ICJ Reports 16 at pp 56-57, paras 126, 131.

¹⁵ Customary international law is the body of general practices recognized, with substantial uniformity, by States as being required by prevailing international law (the existence of an *opinio juris*. See: Ian Brownlie. *Principles of Public International Law* (5th ed). Oxford: Oxford University Press, 1998.

¹⁶ UDHR, Article 25(1) [emphasis added]

¹⁷ UDHR, Article 27(1).

¹⁸ JP Humphrey. "The Universal Declaration of Human Rights: Its History, Impact and Judicial Character," in: *Human Rights: Thirty Years After the Universal Declaration* (BG Ramcharan, ed). The Hague: Martinus Nijhoff, 1984; I Brownlie. *Principles of Public International Law* (5th ed). Oxford: Oxford University Press, 1998, at 574-75; H Hannum. "The Status of the Universal Declaration of Human Rights in National and International Law." *Georgia Journal of International & Comparative Law* 1995: 287 (article by the Rapporteur of the Committee on the Enforcement of International Human Rights Law of the International Law Association); Resolution of the International Law Association, adopted at the 66th ILA Conference, Buenos Aires, 1994.

¹⁹ *Vienna Declaration and Programme of Action*, UN GAOR, World Conference on Human Rights, 78th Session, 22nd plenary meeting, UN Doc. A/CONF/157/23 (1993): Part I, Article 1.

physical and mental health."²⁰ The companion treaty, the *International Covenant on Civil and Political Rights*, recognizes the rights to life and to security of the person.²¹

Other UN system conventions further elaborate the right to health, with respect to particular populations. Under the *International Convention on the Elimination of All Forms of Racial Discrimination* (CERD), States undertake to guarantee everyone's "right to public health, medical care, social security and social services" without discrimination based on race, colour, national or ethnic origin.²² Under the *Convention on the Elimination of All Forms of Discrimination Against Women* (CEDAW), States are obliged to "take all appropriate measures" to ensure, on a basis of equality of men and women, "access to health care services, including those related to family planning."²³ And under the *Convention on the Rights of the Child*, States recognize the child's right to the highest attainable standard of health "and to facilities for the treatment of illness and rehabilitation of health." To this end, States "shall strive to ensure that no child is deprived of his or her right of access to such health care services," and "shall take appropriate measures" to diminish infant and child mortality, ensure the provision of necessary medical assistance and health care, to combat disease (including through applying readily available technology), and to ensure appropriate pre- and post-natal health care for mothers.²⁴ Various regional human rights instruments in the inter-American, African and European human rights systems also recognize a right to health in international law.²⁵

But one difficulty, particularly with respect to legal enforcement of such a right, lies in determining its content. "There would be no justification for elevating a 'claim' to the status of a right (with all the

²⁰ ICESCR, Article 12.

²¹ ICCPR, Articles 6 and 9.

²² CERD, 660 UNTS 195 (entered into force 1969): Article 5(e)(iv). The Durban Declaration and Programme of Action, adopted at the World Conference Against Racism, also urges State action "to take concrete measures, including ... appropriate access to medication and treatment, ... to eliminate ... negative consequences arising from these pandemics [such as HIV/AIDS]", "to promote access without discrimination to health care," and "to take steps to ensure equal access to comprehensive, quality health care affordable for all, including primary health care for medically underserved people...": Programme of Action, paragraphs 3, 101 & 110.

²³ CEDAW, 1249 UNTS 13 (entered into force 1981): Article 12. See also: 1995 Beijing Declaration and Platform for Action, UN Doc A/CONF.177/20; General Recommendation No. 24 of the Committee on the Elimination of Discrimination Against Women (adopted in 1999, available via: www.unhcr.ch); Audrey R Chapman. "Monitoring Women's Right to Health Under the International Covenant on Economic, Social and Cultural Rights." *American University Law Review* 44: 1157 (available at: www.law-lib.utoronto.ca/Diana/fulltext/CHAP.htm).

²⁴ CRC, 1577 UNTS 3 (entered into force 1990): Articles 23, 24 and 27.

²⁵ See: *African Charter on Human and Peoples' Rights* (adopted 27 June 1981 by the Organization of African Unity, entered into force 21 October 1986), Article 16; the *African Charter on the Rights and Welfare of the Charter* (adopted 11 July 1990, entered into force 29 November 1999), Article 14; *European Social Charter*, Part I and Part II (Articles 11 & 13). See also the *American Declaration on the Rights and Duties of Man* (adopted 2 May 1948 by the Organization of American States), Article 11. The *Declaration* is not a treaty, but the OAS adopted a protocol in 1967 making it binding on all states which are parties to the OAS Charter: *Protocol of Buenos Aires* (1970), 721 UNTS 324. An additional protocol explicitly recognizes the right to health, affirms that health is a "global public good", and requires States which are parties to adopt measures to extent the benefits of health services to all individuals, prevent and treat diseases, and satisfy the health needs "of the highest risk groups and of those whose poverty makes them the most vulnerable": *Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights* ("Protocol of San Salvador"), 14 November 1998, OAS TS 69 (1988). The *Cairo Declaration on Human Rights in Islam* (adopted 5 August 1990 by the Organization of the Islamic Conference) recognizes the right of everyone "to medical and social care" and that the State "shall ensure the right of the individual to a decent living which will enable him to meet all his requirements and those of his dependents, including... medical care...": Article 17.

connotations that concept is generally assumed to have) if its normative content could be so indeterminate as to allow for the possibility that the right-holders possess no particular entitlement to anything."²⁶

Article 12 of the ICESCR sets out some specific steps to be taken by States Parties to achieve the full realization of this right. This non-exhaustive list includes those steps necessary for:

- (a) the provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; [...]
- (c) the prevention, treatment and control of epidemic, endemic, occupational and other diseases;
- (d) the creation of conditions which would assure to all medical service and medical attention in the event of sickness.

Building on this, the most detailed articulation of the content of the right to health in international law is found in General Comment 14 of the UN Committee on Economic, Social & Cultural Rights, which provides an authoritative expert interpretation of the right as set out in Article 12 of the ICESCR. Beginning with the broad premise that "the right to health must be understood as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health, the Committee notes that the right to health contains four interrelated and essential elements: availability, accessibility, acceptability, and quality. With respect to the second element, "accessibility", there are four overlapping dimensions including *economic* accessibility (ie, affordability):

[H]ealth facilities, goods and services must be affordable for all. Payment for health-care services, as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households shall not be disproportionately burdened with health expenses as compared to richer households.²⁷

Applying a tripartite typology now established in international law, the Committee observes that, as with all human rights, the right to health imposes on States:

...the obligations to *respect*, *protect* and *fulfil*. In turn, the obligation to fulfil contains obligations to facilitate, provide and promote. The obligation to *respect* requires States to refrain from interfering directly or indirectly with the enjoyment of the right to health. The obligation to *protect* requires States to take measures that prevent third parties from interfering with article 12 guarantees. Finally, the obligation to *fulfil* requires States to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health. [...]

Obligations to *protect* include, *inter alia*, the duties of States to adopt legislation or to take other measures ensuring equal access to health care and health-related services provided by third parties;

²⁶ Philip Alston & Gerard Quinn. "The Nature and Scope of States Parties' Obligations Under the International Covenant on Economic, Social and Cultural Rights." *Human Rights Quarterly* 1987; 9(2): at 352.

²⁷ UN Committee on Economic, Social & Cultural Rights. "General Comment 14: The right to the highest attainable standard of health (Art. 12)", 4 July 2000, UN Doc E/C.12/2000/4, CESCR: at para 12 (available via: www.unhcr.ch).

to ensure that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services; to control the marketing of medical equipment and medicines by third parties; ...

The obligation to *fulfil* requires States parties, *inter alia*, to give sufficient recognition to the right to health in the national political and legal systems, preferably by way of legislative implementation, and to adopt a national health policy with a detailed plan for realizing the right to health. [...]

The obligation to *fulfil (facilitate)* requires States *inter alia* to take positive measures that enable and assist individuals and communities to enjoy the right to health. States parties are also obliged to *fulfil (provide)* a specific right contained in the Covenant when individuals or a group are unable, for reasons beyond their control, to realize that right themselves by the means at their disposal. The obligation to *fulfil (promote)* the right to health requires States to undertake actions that create, maintain and restore the health of the population. ...²⁸

In April 2002, the UN Commission on Human Rights unanimously decided to appoint a Special Rapporteur on the right to health, with a 3-year mandate to report on laws and policies that support the realization of this right as well as domestic and international obstacles to its realization.²⁹ This provides an additional mechanism for advocacy, within the UN system and at the domestic level, for reform of law and policy aimed at improving access to treatment.

III. ACCESS TO MEDICINES AS AN ELEMENT OF THE RIGHT TO HEALTH

Beyond the references in the ICESCR and in CESCR's General Comment 14, there have been some recent developments in international law specifically addressing the question of access to medicines as a component of the right to health.

The *International Guidelines on HIV/AIDS and Human Rights*, adopted by the UN Office of the High Commissioner of Human Rights and UNAIDS in 1998, were the product of an international consultation of experts in 1996.³⁰ Guideline 6 provides that "States should enact legislation to provide for the regulation of HIV-related goods, services and information, so as to ensure widespread availability of qualitative prevention measures, adequate HIV prevention and care information and safe and effective medication at an affordable price." The Guidelines are not legally binding, but have been repeatedly noted by the UN Commission on Human Rights, which has "invited" states to take all necessary steps to ensure the respect, protection and fulfilment of HIV-related human rights as contained in the Guidelines, and has "urged" states to ensure their laws, policies and practices promote effective programs for care and support, "including through equitable access to safe and effective medication for the treatment of HIV infection and HIV/AIDS-related illnesses."³¹

²⁸ General Comment 14, paras. 33, 35, 36 & 37.

²⁹ UN Commission on Human Rights, Resolution 2002/31.

³⁰ Available via: www.unaids.org or www.unhchr.ch.

³¹ UN Commission on Human Rights, Resolution 2001/51.

More recently, significant developments have occurred at the UN and at the World Trade Organization that indicate an evolving recognition in international law that countries must make medicines to treat pandemics such as HIV/AIDS more accessible.

The UN Commission on Human Rights has now adopted, at successive sessions, two resolutions declaring that "access to medication in the context of pandemics such as HIV/AIDS is one fundamental element" for realizing the right to health.³² The resolutions further call upon States "to pursue policies which would promote the availability and affordability of medicines and medical technologies", and "to ensure that the application of international agreements is supportive of public health policies promoting broad access to safe, effective and affordable pharmaceuticals and technologies." The second resolution, adopted unanimously in 2002, also replicates verbatim the first four paragraphs of the WTO's declaration in November 2001 (see below).

Similar language can be found in the *Declaration of Commitment on HIV/AIDS* adopted as a resolution of the UN General Assembly in June 2001, wherein the member states of the UN "recogniz[ed] that access to medication in the context of pandemics such as HIV/AIDS is one of the fundamental elements to achieve progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." They committed to "in an urgent manner make every effort to provide progressively and in a sustainable manner, the highest attainable standard of treatment for HIV/AIDS, including the prevention and treatment of opportunistic infections, and effective use of quality-controlled anti-retroviral therapy in a careful and monitored manner to improve adherence and effectiveness and reduce the risk of developing resistance."³³ Strictly speaking, the Declaration has no legal effect, but provides further evidence of an emerging international law norm that access to medication is part of a legally binding human right, whose enforcement by domestic and international tribunals is gradually gaining ground.

More recently, the World Trade Organization has been the site of some developments of potentially considerable significance for the struggle to gain access to treatment in developing countries. In November 2001, the 4th Ministerial Conference of the WTO adopted a "Declaration on the TRIPS Agreement and Public Health" (the "Doha Declaration").³⁴ That Declaration states that the WTO's agreement on patents, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) "does not and should not prevent [WTO] Members from taking measures to protect public health." It also affirms that the TRIPS Agreement "can and should be interpreted in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." Furthermore, "in applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles." This is important, because the "principles" stated in Article 8 include recognition that countries may "adopt measures to necessary to protect public health", and "to promote the public interest in sectors of vital importance to their socio-economic and technological development", and may need to take appropriate measures "to prevent the abuse of

³² UN Commission on Human Rights, Resolutions 2001/33 (23 April 2001) and 2002/32 (22 April 2002), available via: www.unhchr.ch.

³³ UN General Assembly. *Declaration of Commitment on HIV/AIDS*, : Paras 15 & 55.

³⁴ Available via www.wto.org. For an overview of the TRIPS Agreement and its relation to the issue of access to medicines, see: R Elliott & MH Bonin. "Patents, International Trade Law and Access to Essential Medicines," an info sheet prepared for Canadian HIV/AIDS Legal Network & Médecins Sans Frontières Canada, May 2002 via www.aidslaw.ca (aussi disponible en français).

intellectual property rights by right holders” or to prevent “resort to practices which unreasonably restrain or adversely affect the international transfer of technology.”

On balance, the Doha Declaration is a welcome development for treatment activists, and it carries legal weight. It recognizes that WTO member countries have a "right to protect public health", thereby establishing a norm of customary international law. It provides clear ministerial direction for the correct interpretation of the TRIPS Agreement, and under WTO treaty law³⁵ and the accepted rules of treaty interpretation (in customary international law, as codified in the *Vienna Convention on the Law of Treaties*)³⁶ that direction must be given legal effect.

It remains to be seen to what effect this instrument will have in future on the interpretation and application of the TRIPS Agreement, both by WTO panels and appellate body and as a ripple effect in the interpretation by domestic courts of national patent laws and human rights laws in cases where private patent rights are ranged against the broader public interest in promoting access to more affordable medicines. Unfortunately (but not surprisingly), there is no express reference in the Doha Declaration to human rights as vested in real people (but rather a reference to the right of states "to protect public health"). Nonetheless, it represents a significant step forward in international law, boosting efforts to inject human rights considerations into other areas.

IV. LITIGATING THE RIGHT TO HEALTH

Advancing the right to health as a notionally binding norm in international law is important, but this "of course, can only go a limited distance in achieving the desired objectives of social justice. The importance of economic, social and cultural rights taking on a legal life of their own at the domestic level is inestimable. [...] While much of the reliance on global norms stems from difficulties connected to the domestic applicability or direct validity of international human rights texts within the national legal order, it will only be through increasing the incorporation of international norms within national legal structures, coupled with the amplification of efforts towards expanding the justiciability and enforcement of socio-economic standards at the local level that violations of these rights can be effectively combatted."³⁷

Litigation aimed at improving access to treatment for people living with HIV/AIDS has generally rested on two kinds of claims, depending on the facts of the case being brought forward: (1) challenges to discrimination in access to health care, and (2) claims to an independent right to health or related right. In some cases, the circumstances give rise to both kinds of claim and both have been advanced (although not always successfully). The remainder of this paper focuses principally on the second category.

(1) Cases challenging discrimination in health care

The first claim is one of *equality* in access to health care. In many cases, it is discrimination in the provision of health care or in health care policy that is the principal barrier to access to treatment, in that people living with HIV/AIDS are denied goods or services generally available. A common example

³⁵ *Agreement Establishing the World Trade Organization* (adopted 15 April 1994), Articles IV(1) and IX(2).

³⁶ Article 31 of the VCLT states that treaty terms must be given their "ordinary meaning...in their context". Article 31(3) expressly specifies that, together with the "context", the treaty interpreter "shall" take into account "any subsequent agreement regarding the interpretation or application of the treaty's provisions."

³⁷ Scott Leckie. *Violations of Economic, Social and Cultural Rights. SIM Special No. 20*, [add page ref]

would be a proceeding against a health care professional for refusing to treat a person because of their HIV-positive status.³⁸ There have been many such cases, in both developed and developing countries, reflecting both the prevalence of such discrimination and the fact that the domestic law of most countries includes provisions prohibiting such discrimination which can be enforced through various mechanisms, including court judgments. Such claims have generally been the strongest and enjoyed the greatest chance of success.

Another example would be a claim against an existing public program or private insurance scheme that refuses or fails to provide or pay for HIV/AIDS-related treatment, or imposes discriminatory restrictions upon such treatment if included. Such cases have generally witnessed a more mixed track record. Legislation exists in many jurisdictions aimed at facilitating the discrimination against "bad risk" that is the fundamental operating principle of private, for-profit insurers; this often provides strong defenses against discrimination claims.³⁹ In other countries, legislation is more progressive, and may actually oblige private insurance companies to cover HIV/AIDS-related treatment.⁴⁰ In the case of public programs, judicial deference to governments in the allocation of resources has also been a hurdle. The greatest success with the use of anti-discrimination law has been where existing public programs have applied existing criteria in a discriminatory fashion or have been implemented in a fashion that discriminatorily excludes people on some prohibited basis.⁴¹

(2) Cases claiming an independent right to health or related right

The second category of cases consists of those which claim an independent right to health (or some similar right) that imposes a positive obligation on government to provide health care goods or services, rather than simply seeking to remedy HIV/AIDS-based discrimination in the delivery, application or implementation of existing services or programs. Admittedly, the distinction between this and the first category is not always clear — indeed, in many cases, both a claim to equality and to health may be advanced, and the arguments may often overlap. This is not surprising, given that stigma and discrimination may often be the underlying basis for government inaction in relation to HIV/AIDS, meaning that both claims are appropriate. What distinguishes these cases however, is that they seek to vindicate a right to health as a free-standing right giving rise to an entitlement in and of itself, rather than seeking to advance that right solely or principally by characterizing the denial of health care goods or services as discrimination.

³⁸ Eg, *Ahamefule v Imperial Medical Center & Another* is a landmark case in Nigeria in which the Social and Economic Rights Action Centre (SERAC) is representing a woman living with HIV in her suit over the denial of medical care (among other things) based on her HIV status. The case was initiated in 2000 but the a decision on the merits has been delayed by subsequent discrimination by the trial judge in the conduct of the case. See: F Morka. "Nigeria - Judge denies woman with HIV access to courtroom." *Canadian HIV/AIDS Policy & Law Review* 2001; 6(1/2): 77-78.

³⁹ Eg, *John Doe & Richard Smith v Mutual of Omaha Insurance Company*, 179 F.3d 557 (US Court of Appeals, 7th Circuit, 1999).

⁴⁰ Eg, In Argentina, Law 24754 ("Compulsory Medical Services") requires all private medical schemes to provide treatment and medicines to people living with HIV/AIDS: M Bianco et al. "Human rights and access to treatment for HIV/AIDS in Argentina." Series of Case Studies on Human Rights. LACCASO, 1999. Similar legislation exists in Brazil, although this has not precluded over 400 cases having been brought by NGOs against private health insurance companies to secure coverage for HIV/AIDS medications: NGO perspectives on access to HIV-related drugs in 13 Latin American and Caribbean countries. Geneva: UNAIDS, 1998: at 15.

⁴¹ Eg., *Eldridge v British Columbia (Attorney General)*, [1997] 3 SCR 624 (decision of Supreme Court of Canada ruling that government unconstitutionally discriminated against deaf people on the basis of disability by failing to pay for sign language interpretation needed to access hospital and other health services under its publicly funded medicare program).

Efforts to enforce health-related entitlements through legal action have been relatively sparse, frequently hindered by the difficulty (greater in some legal systems than others) in enforcing international law norms, the absence of domestic law provisions implementing a right recognized in international law into entitlements enforceable by domestic courts, and the general ideological hostility or indifference of governments and many judges to recognition of any enforceable "right" to health. Nonetheless, there have been some efforts, putting the lie to the claim that such rights are not "justiciable".

Interestingly, the most successful litigation has generally arisen from activists in developing countries and much of it has occurred very recently, in the context of efforts to use the courts to gain access to medicines for people living with HIV/AIDS. Litigation has also occurred before regional human rights bodies, although with less specificity of result. Latin American activists have been particularly successful with such strategies, resulting in significant gains for numerous people living with HIV/AIDS (although limits on health budgets and bureaucratic inefficiencies continue to remain a common problem that often frustrates proper compliance with court orders obtained).⁴²

Not surprisingly, such efforts have been most successful where the right to health finds some purchase in domestic constitutional law — the strongest possible basis for enforcing a legal claim. According to the Commonwealth Human Rights Initiative, among Commonwealth countries (inheriting the British common law system), only a handful of constitutions recognize the right to health in some fashion — a scant few create a clearly justiciable right,⁴³ a greater number recognize it merely as a directive principle for state policy,⁴⁴ and most contain no mention of it.⁴⁵ According to an early study by the Pan American Health Organization,⁴⁶ none of the common law countries in the Americas include a right to health in their constitutions, but many of the civil law⁴⁷ and all of the socialist law⁴⁸ countries do. Some European civil law countries either refer to a right to health (in some form) specifically, or set out state obligations regarding health.⁴⁹ The constitutions of sub-Saharan African countries generally expressly recognize a right to social security or protection in some form, and generally specify a State obligation to promote and protect health (although often characterized as directive principles rather than clearly justiciable entitlements).⁵⁰

⁴² See: Edgar Carrasco, *Acción Ciudadana Conral el SIDA (ACCSI)*, Venezuela. "Derechos Humanos y el Acceso a Antirretrovirales en América Latina y el Caribe." January 2001, on file.

⁴³ Eg, Mozambique, South Africa.

⁴⁴ Eg, Bangladesh, Guyana, India (although note discussion below about the approach of Indian courts in actually rendering a right to health justiciable), Lesotho, Malawi, Namibia, Nigeria, Niue, Sierra Leone, Sri Lanka, Zambia.

⁴⁵ Eg, Antigua & Barbuda, Australia, Bahamas, Barbados, Belize, Botswana, Brunei Darussalam, Cameroon, Canada, Cook Islands, Cyprus, Dominica, Fiji Islands, Gambia, Ghana, Grenada, Jamaica, Kenya, Kiribati, Malaysia, Maldives, Malta, Mauritius, Nauru, New Zealand, Pakistan (constitution suspended), Samoa, Seychelles, Singapore, Solomon Islands, St Kitts & St Nevis, St Lucia, St Vincent & the Grenadines, Swaziland, Tonga, Trinidad & Tobago, Tuvalu, Uganda, United Kingdom, Tanzania, Vanuatu, Zimbabwe.

⁴⁶ Pan American Health Organization (PAHO). *The Right to Health in the Americas*. Washington DC: PAHO, 1989 (Scientific Publication No. 509).

⁴⁷ Eg, Bolivia, Chile, Ecuador, Guatemala, Haiti, Honduras, Mexico, Panama, Paraguay, Peru, Suriname, Venezuela. Nicaragua adopted a civil law system in the 1990s following political changes; the current constitution recognizes a right to health.

⁴⁸ Eg. Cuba, Guyana.

⁴⁹ Eg, Constitution of Hungary, Article 70/D recognizes "the right to the highest possible level of physical and mental health", clearly modelled on the ICESCR: referenced in Brigit CA Toebe. *The Right to Health as a Human Right in International Law*. Antwerp: Intersentia-Hart, 1999, at p. 82.

⁵⁰ See: Têtêvi Dodzi Agbodjan. "Le droit à la santé en Afrique subsaharienne: vers des soins communautaires et/ou une assurance maladie?" Seminar presented to the Centre Études internationales et Mondialization, Université du Québec à

Litigation within international or regional human rights systems

There has been little in the way of either legal judgments or soft law ("opinions" or "recommendations") on the right to health from international human rights mechanisms under international treaties.

ICESCR

There is no "case law" under the ICESCR for the simple reason that there is no complaints mechanism. The only means of raising concerns about the right to health is during the periodic reporting by States to the Committee on Economic, Social & Cultural Rights, which happens only every 5 years (and is often ignored by many signatory states). However, efforts to establish a complaints mechanism via an Optional Protocol to the ICESCR continue, which would provide one avenue for "litigating" the right to health.

European human rights system

In the 1997 *Case of D v United Kingdom*,⁵¹ the European Court of Human Rights decided that it would amount to "inhuman treatment" under the *European Convention on Human Rights* for the United Kingdom to deport a man in the late stage of AIDS back to his home country of St. Kitts, where he would face poor general public health conditions and lack of access to treatment for AIDS.

African human rights system

The communications procedure contemplated in the *African Charter on Human and Peoples' Rights* has yielded one case in which the right to health in that instrument has received some consideration. In *World Organisation Against Torture, Lawyers' Committee for Human Rights, Les Témoins de Jéhovah, & Union Interafricaine des Droits de L'Homme v Zaire*, the petitioning NGOs made numerous allegations various human rights violations, ranging from arbitrary arrests, detention in torture and religious persecution to the shortage of medicines and the failure of government to provide basic services such as safe drinking water and electricity. As summarized by Carbert et al:

The Commission found that the right to health includes the duty of government to provide services such as safe drinking water, electricity and medicine. The Commission referred to Article 16 of the African Charter, which states, "every individual shall have the right to enjoy the best attainable state of physical and mental health." The Commission decided that the government's failure "to provide basic services necessary for a minimum standard of health, such as safe drinking water and electricity, and the shortage of medicine" constitutes a violation of Article 16.⁵²

Inter-American human rights system

There have been a several cases brought before the Inter-American Commission on Human Rights implicating the right to health.⁵³

Montréal, May 2002 (available via: www.cedim.uqam.ca), with reference to: de Gaudusson et al. *Les constitutions africaines*, Paris: La Documentation Française, 1997.

⁵¹ European Court of Human Rights, 2 May 1997, Case No. 146/1996/767/964 (available via: www.echr.coe.int).

⁵² Communications 25/89, 47/90, 56/91, 100/93, 19th Session of the African Commission on Human and Peoples' Rights, March 1996, cited in: A Carbert et al. *A Handbook for Advocacy in the African Human Rights System: Advancing Reproductive and Sexual Health*. Toronto & Nairobi: International Programme on Reproductive and Sexual Health Law, University of Toronto Faculty of Law & Ipas Kenya, February 2002: at 65.

⁵³ None of the cases proceeded to be decided by the Inter-American Court.

In the *Ache Tribe Case* (1977),⁵⁴ the complainants alleged that the Government of Paraguay had, among other things, withheld medical treatment and medicines during infectious disease epidemics. The Commission ruled that the government's conduct amounted to "grave violations" of numerous rights of the Ache people, including the right to the preservation of health under Article XI of the *American Declaration on the Rights and Duties of Man*. However, there was no detailed analysis of the right.

In the *Yanomami Tribe Case* (1985),⁵⁵ the complainants alleged that, through its program of road-building in the Amazon, the Government of Brazil had violated their right to preservation of health under the American Declaration, among other rights. As a result of the road-building, Yanomami were exposed to epidemics such as influenza, TB, measles, venereal diseases and others, and they argued the government had not adequately taken action to address these health crises. The Commission agreed, finding that Brazil had violated the right to the preservation of health. The Commission "recommended" that, among other things, "the Government of Brazil continue to take preventive and curative health measures to protect the lives and health of Indians exposed to infectious or contagious diseases." There was no detailed discussion of the right to health.

The Commission has also found violations of the right to preservation of health and well-being in several cases where the Government of Cuba detained people under inhumane conditions, including inadequate medical care and food.⁵⁶ However, the lack of access to medical care was but one factor, and did not receive detailed discussion.

One case dealing with access to HIV/AIDS treatment has yielded a "decision" via the Inter-American regional system (although a second has been communicated). In January 2000, in the case of *Odir Miranda et al v El Salvador*, 27 people living with HIV/AIDS filed a petition alleging that the Government of El Salvador had violated their rights under the *American Convention on Human Rights* to life, humane treatment, equal protection before the law, judicial protection, and economic, social and cultural rights. They also alleged violation of Article 10 of the *Protocol of San Salvador* and other provisions of the *American Declaration on the Rights and Duties of Man*. The basis of the complaint was the State's failure to provide them with combination anti-retroviral therapy necessary to prevent death and improve quality of life. They further alleged that that the failure to provide the necessary treatment constituted discrimination against them based on their HIV-positive status by the Salvadoran Social Security Institute.

The petitioners had previously initiated *amparo*⁵⁷ proceedings in the courts of El Salvador. Although the Supreme Court (Constitutional Division) accepted the petition in June 1999, it delayed in rendering a

⁵⁴ Case 1802—Paraguay, in *Annual Report of the Inter-American Commission on Human Rights 1977*, 20 April 1978, OEA/Ser.L/V/II.43.

⁵⁵ Resolution No. 12/85, Case 7615—Brazil, in *Annual Report of the Inter-American Commission on Human Rights 1984-1985*, 5 March 1985, OEA/Ser.L/V/II.66.

⁵⁶ *Valladares v Government of Cuba*, Case 2300—Cuba (1982), in *Annual Report of the Inter-American Commission on Human Rights 1981-1982*, OEA/Ser.L/V/II.57 (Doc 6, rev 1); *Aleman Pelaez et al v Cuba*, Case 4677—Cuba (1981), in *Annual Report of the Inter-American Commission on Human Rights 1981-1982*, OEA/Ser.L/V/II.54 (Doc 9, rev 1); *Capote Rodriguez et al v Cuba*, Case 4429—Cuba (1981), in *Annual Report of the Inter-American Commission on Human Rights 1980-1981*, OEA/Ser.L/V/II.54 (Doc 9, rev 1); *Political Prisoners of Combinado del Este Prison v Cuba*, Case 4402—Cuba (1981), in *Annual Report of the Inter-American Commission on Human Rights 1980-1981*, OEA/Ser.L/V/II.54 (Doc 9, rev 1).

⁵⁷ *Amparo* is a remedy in Latin American civil law systems best described in the terms of a common law system as a "constitutional injunction" - that is, an injunction sought urgently to redress an existing, or prevent an imminent, breach

decision. Given this delay frustrating the petitioners' efforts to seek a remedy under domestic legislation, on 29 February 2000 the Inter-American Commission ordered, as an interim measure, the Salvadoran government to

provide medical attention necessary to protect the life and health of Jorge Odir Miranda Cortéz and the other 25 [petitioners]... In particular the Commission solicits that your illustrious government provide anti-retroviral medications necessary to avoid the death of the aforementioned persons, as well as hospital attention, other medications and nutritional support which strengthen the immune system and impede the development of illnesses and infections.⁵⁸

The order was valid for 6 months while the legal proceedings continued before the Commission. After further submissions and consideration, in March 2001 the Commission declared the case admissible, noting that the almost two years had elapsed since the Salvadoran Supreme Court had received the petition. In April 2001, presumably prompted by the Inter-American Commission's criticism, the Supreme Court of Justice of El Salvador issued a ruling on Miranda's *amparo* claim, based on his claims to right to life and to health, ordering the Salvadoran Social Security Institute to provide him with anti-retroviral therapy. The complaint before the Inter-American Commission was rendered moot and has not proceeded to a hearing on its merits.

Litigation before national courts

In contrast to the relative absence of international cases interpreting and applying the right to health, there is a significantly larger (albeit still small) body of case law from national courts in which individuals and NGOs have sought to enforce such a right. This section provides an overview of several such cases, with a particular emphasis on litigation dealing specifically with the issue of access to medicine (and in particular treatment for HIV/AIDS). It should be noted that the relationship between international law and domestic law is a two-way street. International law norms be either directly enforceable or serve as interpretive guides in domestic law. And decisions of national courts constitute both a recognized, subsidiary means of interpreting international law⁵⁹ and evidence of evolving norms of customary international law.

• India

The Indian Constitution guarantees "fundamental rights" to all citizens, and incorporates "Directive Principles of State Policy" (many of which correspond to ICESCR provisions) which are stated to not be

of constitutional rights. It is similar to a *writ of habeas corpus* known to common law systems, but with a broader application than simply challenging the legality of a person's detention or imprisonment.

⁵⁸ ATLACATL & Asociación Agua Buena. "Inter-American Human Rights Commission Orders El Salvador to Provide Anti-Retroviral Therapy" [media release], 1 March 2000; R Stern. "La Comisión Interamericana de Derechos Humanos Ordena a El Salvador Que Suministre Medicamentos Contra el HIV." *Artículos*, Agua Buena Asociación, 1 March 2000, available at: www.aguabuena.org/articulos/salvador.html.

⁵⁹ *Statute of the International Court of Justice*, Article 38(1).

enforceable by the courts.⁶⁰ The Supreme Court has interpreted the right to health as forming part of the right to life guaranteed in the Indian Constitution, meaning it is legally enforceable.⁶¹

In the case of *Paschim Banga Khet Majoor Samity v State of West Bengal*,⁶² the Supreme Court declared the right to health a fundamental, ordered the state government to pay the plaintiff compensation for the harm suffered by denial of medical care, and instructed the government to develop a plan for primary health care. In another case, the Court concluded that workers' fundamental right to health required a scheme of compulsory health insurance.⁶³ The Court has exercised its authority to protect the right to health by banning medications of substandard quality.⁶⁴ The Court has, however, also recognized that government may fix a scale for its coverage of health expenditures, in line with the extent of its finances.⁶⁵

• Latin America

Activists in numerous countries in Latin America have successfully brought legal proceedings to compel national governments to provide coverage for anti-retrovirals (and other medicines and diagnostics) for people living with HIV/AIDS under public or private health insurance programs. In a minority of cases, legal action has been unsuccessful, although advocacy efforts are ongoing. In other countries (eg, Uruguay), lobbying has led to legislation and policy including anti-retrovirals and other needed treatments in public health insurance schemes.⁶⁶ The experience, however, has been that ongoing advocacy (including sometimes further legal proceedings) are necessary to ensure compliance with court orders.⁶⁷

Argentina

In 1996, eight NGOs brought an *amparo* action against the National Ministry of Health and Social Welfare for its failure to supply medicines to people living with HIV/AIDS. Within three days, the court ordered the Ministry to provide medication.⁶⁸ In early 1998, NGOs brought a second *amparo* proceeding on behalf of numerous people living with HIV/AIDS against both the Ministry and the social security system (which cover medical care for different segments of the population) for failure to supply anti-retrovirals. The court of first instance and the appellate court granted the request and ordered that authorities provide medicines in a timely and uninterrupted fashion to people living with HIV/AIDS eligible for coverage under these programs. These two decisions were affirmed by the Supreme Court of Justice in February 1999.⁶⁹

⁶⁰ Part of this summary is based on: "Justiciability of ESC Rights - the Indian Experience" in *Circle of Right—Economic, Social & Cultural Rights Activism: A Training Resource*. University of Minnesota Human Rights Resource Centre (International Human Rights Internship Programme), 2000 (available at: www.hrusa.org/hrmaterials/IHRIP/circle/toc.htm).

⁶¹ *Francis Coralie Mullin v The Administrator, Union Territory of Delhi* (1981) 2 SCR 516. See also: *Parmanand Katara v Union of India* (1989) 4 SCC 286; *State of Punjab and others v Mohinder Singh Chawla and others* 1997 AIR 1225 (Supreme Court of India).

⁶² (1996) 4 SCC 37.

⁶³ *Consumer Education and Research Centre v Union of India* (1995) 3 SCC 42.

⁶⁴ *Vincent Pannikulangura v Union of India* (1987) 2 SCC 165; *Drug Action Forum v Union of India* (1997) 6 SCC 609; and several other cases.

⁶⁵ *State of Punjab v Ram Lubhaya Bagga* (1998) 4 SCC 117.

⁶⁶ Carrasco, *supra* at 5.

⁶⁷ Carrasco, *supra* at 18; MA Torres, *supra*.

⁶⁸ M Bianco et al. Human rights and access to treatment for HIV/AIDS in Argentina. Series of Case Studies on Human Rights. LACCASO, 1999: at 15.

⁶⁹ *Ibid*.

On 1 June 2000, the Supreme Court of Justice upheld an appellate chamber decision and the original judgment of first instance in an *amparo* proceeding brought by a coalition of HIV/AIDS NGOs, ordering the Minister of Health to ensure a regular, timely and uninterrupted supply of medications to people living with HIV/AIDS through the public health system, as required to give effect to the right to health (described as part of the right to life) as expressly recognized in the national constitution, in the national law on AIDS, and in the *UDHR*, the *American Declaration on the Rights and Duties of Man*, and the *ICESCR*. The government argued the courts below had overstepped their authority, trenching on the power of the executive to make budgetary decisions. The Court rejected this argument.

On 26 April 2002, noting the June 2000 decision of the Supreme Court, a court of first instance in Argentina granted an urgent request for a protective measure ("medida cautelar") on behalf of those people living with HIV/AIDS who receive anti-retrovirals from the AIDS Programme of the national Ministry of Health.⁷⁰ A series of administrative obstacles, including the failure of the Ministry to act in a timely fashion in acquiring medicines and a dispute over the costs, led to the stock being depleted, with consequent interruption in the supply to patients. Represented by the Centre for Legal and Social Studies (CELS), two representative petitioners brought an *acción de amparo*⁷¹ on behalf of themselves and all other people living with HIV/AIDS in a similar situation. They sought a court order that the national government immediately take the steps necessary to ensure the AIDS Programme could guarantee uninterrupted supply of anti-retrovirals. The court granted the order the same day, stating that delay by the government agencies responsible was unjustifiable when the health and lives of people are at stake. The judge ordered the Ministry of Health to immediately provide the prescribed efavirenz, stavudine (d4T) and lamivudine (3TC) to the two petitioners, and with respect to other people living with HIV/AIDS whose interests were represented in the collective *amparo* action, he ordered the Ministry to take the necessary steps within two days to ensure a regular and uninterrupted supply of medicines for the treatment of HIV/AIDS.

Chile

In October 2001, the Supreme Court overturned a lower court ruling ordering the Ministry of Health to provide three people living with HIV/AIDS with coverage of anti-retrovirals under the country's public health insurance scheme. With the assistance of CEJIL, the NGO Vivo Positivo has filed a communication with the Inter-American Commission on Human Rights.⁷²

Colombia

In 1993, the first case was successfully brought against a public health facility that denied medicines to a person living with HIV/AIDS. Subsequent cases have followed, required in part because of the courts'

⁷⁰ *AV & CM v Ministerio de Salud de la Nación*, 26 April 2002, Juzgado en lo Civil y Comercial Federal No. 7.

⁷¹ *Amparo* is a remedy in Latin American civil law systems best described in the terms of a common law system as a "constitutional injunction" - that is, an injunction obtained urgently to redress an existing, or prevent an imminent, breach of constitutional rights. It is similar to a *writ of habeas corpus*, but with a broader application than simply challenging the legality of a person's detention or imprisonment.

⁷² CEJIL. Comunicado de Prensa, 21 noviembre 1001(via: www.cejil.org); Policía reprime a enfermos de sida que claman atención en Chile. *Reuters*, 19 October 2001; El Sida en la justicia. *La Tercera*: Día mundial del SIDA, 2001 (at:www.tercera.cl/especiales/2001/sida/datos/justicia.htm, accessed 17 February 2002); T Vidaurrázaga. Health-Chile: AIDS Funding Falls Short. InterPress Service, 26 February 2001; Carmen Gloria Ramos. Tiempos Modernos: Una amarga espera. *Revista QuePasa* 1481, 30 August 1999 (at: www.quepasa.cl/revista/1481/35.html, accessed 17 February 2002); Carrasco, *supra* at 10.

decision that the remedy could only be applicable to the specific individual(s) bringing the action.⁷³ NGOs were active in lobbying for law reform that led to new national legislation on AIDS being implemented in 1997; that legislation includes anti-retrovirals on the list of medicines which Colombians living with HIV/AIDS are entitled to receive within the national health care system.⁷⁴

⁷³ NGO perspectives on access to HIV-related drugs in 13 Latin American and Caribbean countries. Geneva: UNAIDS, 1998: at 14-15.

⁷⁴ NGO perspectives on access to HIV-related drugs in 13 Latin American and Caribbean countries. Geneva: UNAIDS, 1998: at 10.

Costa Rica

Costa Rica saw the first case seeking access to treatment in 1992, when several people living with HIV/AIDS applied to the Supreme Court for an order that the government provide AZT. The appeal was denied on the grounds of insufficient evidence as to the difference it would make for patients, and the high cost in relation to benefits achieved.⁷⁵ Further litigation followed in July 1997, when several people applied to the Supreme Court for an order compelling the government to provide anti-retrovirals medically prescribed by physicians, citing the constitution and international human rights treaties. The Court granted the request, ordering the government to provide ARVs to those in need. The Court ruled that the cost could not outweigh the right to life and health, and that providing such medicines was an obligation of the state.⁷⁶ This led soon after to the national health system covering providing anti-retrovirals for all people with HIV/AIDS.

El Salvador

The case of *Odir Miranda et al* has been discussed above, in relation to the petitioners' application to the Inter-American Commission on Human Rights. It should also be noted that, despite numerous deficiencies breaching a variety of human rights, El Salvador's new *Law on the Prevention and Control of the Infection caused by the Human Immunodeficiency Virus* affirms the right of every person living with HIV/AIDS to "health care, medical, surgical and psychological treatment", as well as counselling and "preventive measures to impede the progress of the infection."⁷⁷

Mexico

Both lobbying and litigation (in the form of *amparo* actions) have led the state to recognize its obligations to provide access to anti-retrovirals for people living with HIV/AIDS.⁷⁸

Panama

Although in May 1999 the Supreme Court rejected a case brought by people living with HIV/AIDS, seeking coverage for anti-retrovirals under the national social security system, as a result of ongoing protests the government decided to extend coverage to both those entitled to social security and to those with no such health insurance. The decision made Panama the second Central American country (after Costa Rica) to provide ARV coverage.⁷⁹

Peru

In early May 2002, four Peruvians living with HIV/AIDS, supported by the NGO Agora filed *amparo* proceedings against the Peruvian government, demanding access to ARVs. A doctor with the Asociación Via Libre de Perú notes that about 8-10,000 people living with HIV/AIDS in Peru currently need access to treatments, but only about 1000 people receive them through social security, 200 others through their

⁷⁵ NGO perspectives on access to HIV-related drugs in 13 Latin American and Caribbean countries. Geneva: UNAIDS, 1998: at 14.

⁷⁶ NGO perspectives on access to HIV-related drugs in 13 Latin American and Caribbean countries. Geneva: UNAIDS, 1998: at 14.

⁷⁷ *Law on the Prevention and Control of the Infection caused by the Human Immunodeficiency Virus* (Decree No 588, 24 October 2001), Article 5(a).

⁷⁸ Carrasco, *supra*; C Garcíade leon y N Diaz Pardo. "Acceso a tratamientos para VIH/SIDA desde la perspectiva de la sociedad civil." Series of Casse Studies on Human Rights, LACCASO, 1999.

⁷⁹ R Stern. "Panamanian People with AIDS win Battle for Triple Therapy Treatment!" Release, 18 May 1999.

coverage as members of the armed forces, and a small number purchase them privately. The Ministry of Health estimates that at the end of 1999, there were about 76,000 people living with HIV/AIDS in Peru.⁸⁰

Venezuela

Venezuelan courts, including the highest court in the country, have repeatedly recognized that the government must take positive action to ensure that people living with HIV/AIDS have access to anti-retroviral medicines, to medicines for the treatment of opportunistic infections, and to specialized laboratory tests necessary for the effective treatment of HIV infection and OIs. The courts have found this obligation in the right to life, the right to health, and the right to the benefits of scientific progress.⁸¹

In May 1997, a trial court recognized the right of social security recipients to an uninterrupted provision of anti-retrovirals (including protease inhibitors), and ordered the Venezuelan Social Security Institute (IVSS) to provide such treatment for eligible people with HIV/AIDS.⁸²

In January 1998, in *JRB et al v Ministerio de la Defensa*, a case dealing principally with compulsory HIV testing of military personnel and the disclosure of individuals' private medical information, the Supreme Court of Justice also ordered the National Armed Forces to solicit funds from the legislature for HIV prevention and treatment and to provide needed medical treatments to the HIV-positive petitioners through their military pension plan.⁸³

Later the same year, the Venezuelan Social Security Institute (IVSS) settled a case brought by over 300 people living with HIV eligible for coverage under the national "social security" administration, by agreeing to cover HIV-related medical expenses.⁸⁴

In August 1998, in *NA et al v Ministerio de Sanidad y Asistencia Social*,⁸⁵ the Supreme Court made another ruling, this time against the Ministry of Health which failed to ensure coverage for HIV/AIDS medications through the public health care system (covering those who are not eligible for coverage under the "social security" scheme, which is tied to employment-based contributions). The Court ordered the provision of medications to those covered by this program.

In the most significant ruling to date, *Cruz Bermudez et al v Ministerio de Sanidad y Asistencia Social*,⁸⁶ the Supreme Court was considering the same issue as in the previous *NA* case. It again ruled in favour of the *amparo* action brought by over 170 people living with HIV/AIDS, who alleged that the Ministry had failed to supply prescribed ARVs. The petitioners claimed a violation of their rights to life, health, liberty and security of the person, equality, and benefits of science and technology. Although the claims regarding liberty, security of the person and equality were dismissed, on 15 July 1999 the Supreme Court

⁸⁰ Perú: Continúan los esfuerzos por acceso universal a ARV's. *Boletines Informativos: Acceso Centroamérica*, 9 May 2000 (via: www.aguabuena.org).

⁸¹ For more detailed discussion, see: Mary Ann Torres. The Human Right to Health, National Courts and Access to HIV/AIDS Treatment: A Case Study from Venezuela. *Chicago Journal of International Law* 2002; 3(1): 105.

⁸² Carrasco, *supra* at 5.

⁸³ *JRB et al v Ministerio de la Defensa*, Supreme Court of Justice of Venezuela, Case No. 14000, 20 January 1998..

⁸⁴ Mary Ann Torres. Access to Treatment as a Human Right: A Discussion of the Aspects of the Right to Health under National and International Law in Venezuela. LL.M. thesis, 2000, on file.

⁸⁵ *NA et al v Ministerio de Sanidad y Asistencia Social*, Supreme Court of Justice of Venezuela, 14 August 1998.

⁸⁶ *Bermudez et al v Ministerio de Sanidad y Asistencia Social*, 15 July 1999, Supreme Court of Justice of Venezuela, Case No. 15.789, Decision No. 916.

ordered the Minister to seek the necessary budget allocations to comply with its legal obligations as set out in the judgment, and went on to order that, for all Venezuelan citizens and residents, the Ministry must: (1) regularly supply ARVs as prescribed and take measures necessary to ensure uninterrupted supply; (2) cover all tests necessary for using ARVs and for treating opportunistic infections; (3) provide medications necessary for treating opportunistic infections; (4) develop a policy of information, treatment and comprehensive medical assistance for PHAs eligible for social assistance; and (5) undertake research on HIV/AIDS in Venezuela, for the purpose of developing programs and infrastructure to prevent HIV and care for those infected. Importantly, after repeated actions, the Court finally decided that the *amparo* remedy need not be limited to the specific petitioners, but could be extended to benefit all those in a similar situation, as described by the Court.

Most recently, on 6 April 2001, the Supreme Tribunal issued a decisive ruling in *López et al v Instituto Venezolano de los Seguros Sociales*⁸⁷ in favour of 29 people living with HIV/AIDS. The petitioners *amparo* action against the Venezuelan Social Security Institute (IVSS) alleged the IVSS had failed to supply ARVs prescribed for them by medical specialists, had failed to supply them in a regular manner as required by the specialists, and/or had supplied only transcriptase inhibitors and not the protease inhibitors necessary for effective combination therapy. They also alleged the IVSS had failed to pay disability pensions to which they were entitled, with serious consequences for emotional and physical health, and for the health and economic well-being of their families, some of whom were also HIV-positive. Finally, they alleged the IVSS had refused to cover the costs of specialized laboratory tests (eg, lymphocyte count, viral load) necessary for the proper administration of combination therapy.

As in previous cases, they invoked a number of human rights, both in international law and in the Venezuelan Constitution. They argued the failure to provide uninterrupted treatment results in deterioration of the immune system, viral drug resistance, opportunistic infections, mental suffering and death, in breach of their rights to life⁸⁸, health,⁸⁹ and liberty and security of the person.⁹⁰ They also alleged the IVSS had breached their right to social security.⁹¹ Finally, they alleged the IVSS had breached their right to the benefits of scientific progress and its applications, which right they alleged is an inherent right of the human person (although not expressly stated in the Constitution) and is guaranteed by the ICESCR (Article 15), by failing to provide medications and failing to cover necessary laboratory tests for effective treatment of persons living with HIV/AIDS (eg, ELISA, Western blot, viral load, tests necessary for treatment of opportunistic infections).

The Supreme Tribunal affirmed that the IVSS had infringed the petitioners' human rights, and as in the previous *Cruz Bermudez* case, also expanded the scope of the *amparo* remedy to protect all those people living with HIV/AIDS eligible for coverage by the IVSS. It ordered the IVSS to: (1) provide transcriptase and protease inhibitors to patients as prescribed by medical specialists; (2) pay for specialized tests necessary for accessing ARV combination therapy (eg, viral load testing) and other specialized tests reasonably available in the country necessary for treatment of HIV/AIDS and opportunistic infections; and (3) provide the medications necessary for the treatment of opportunistic infections.

⁸⁷ *López v Instituto Venezolano de los Seguros Sociales*, 6 April 2001, Supreme Tribunal of Justice.

⁸⁸ 1961 Constitution of Venezuela, Article 58; Universal Declaration of Human Rights, Article 3; ICCPR Article 6, ICESCR Article 11.

⁸⁹ 1961 Constitution of Venezuela, Article 76; UDHR Articles 12 and 25. [Q: Why not the ICESCR Article 15?]

⁹⁰ 1961 Constitution of Venezuela, Article 60; UDHR 5, ICCPR Article 7.

⁹¹ 1961 Constitution of Venezuela, Article 94; UDHR Article 22, ICESCR Article 9.

Noting the language of the national Constitution (Article 83), the Court concluded that the right to health was constitutionalized as a fundamental social right, and not simply as a State objective. The Constitutional Chamber ruled that the failure to provide an uninterrupted supply of the necessary medications and the failure to cover specialized laboratory tests needed for the use of ARVs and the treatment of opportunistic infections was in violation of the petitioners' rights to health, and threatened their rights to life, to the benefits of science and technology, and to social security.

Brazil

Several instance of litigation in the mid-1990s invoked articles in the Constitution of Brazil establishing the right to life and to health. In July 1996, in a case brought by the NGO Grupo de Apoio à Prevenção à AIDS (GAPA), a judge first recognized a right to access ARVs, and ordered the state to ensure their uninterrupted delivery. The cumulative litigation pressure, and this case in particular, led the Ministry of Health to add protease inhibitors to the list of anti-retrovirals provided free of charge to eligible people living with HIV/AIDS.⁹²

• South Africa

In *Applicant v Administrator, Transvaal*,⁹³ a man with HIV/AIDS who was terminally ill had been receiving a drug preventing blindness from public health authorities, who discontinued the drug on the basis of its toxicity, cost and that it was unregistered. The court applied administrative law principles in setting aside the decision to discontinue supplying the drug, and ordered it be provided. In *Van Biljoen v Minister of Correctional Services*, the court applied the interim Constitution in ordering that HIV-positive prisoners are entitled to receive appropriate ARV therapy at state expenses.⁹⁴

The *Pharmaceutical Manufacturers Association* case, resolved through settlement in April 2001 and therefore not resulting in any judicial precedent, is described below by Berger⁹⁵ as an example of legal process and community mobilization working in tandem to defend legislative measures holding the potential (if ever promulgated by government) to improve access to affordable medicines. More recent developments have included a strong judicial pronouncement on the human right to access HIV/AIDS medicines.

Following up on the strong precedent regarding the justiciability of the constitutional right of access to adequate housing in *Grootboom*,⁹⁶ in December 2001 the High Court of South Africa issued a landmark decision enforcing the right to health. The South African Constitution sets out a "right of access to health

⁹² Edgar Carrasco, ACCSI. "Derechos Humanos y el Acceso a Antirretrovirales en América Latina y el Caribe." January 2001; NGO perspectives on access to HIV-related drugs in 13 Latin American and Caribbean countries. Geneva: UNAIDS, 1998: at 13.

⁹³ *Applicant v Administrator, Transvaal* 1993 (4) SA 720 (W), as summarized by Geoff Budlender, Legal Resources Centre, South Africa, communication 9 May 2002.

⁹⁴ *Van Biljoen v Minister of Correctional Services* 1997 (4) SA 427 (C), as summarized by Geoff Budlender, Legal Resources Centre, South Africa, communication 9 May 2002. The interim Constitution did not provide a general right to health care, but did state prisoners were entitled to adequate medical treatment at state expense.

⁹⁵ See also: Mark Heywood. "Debunking 'Conglomo-talk': A case study of the *amicus curiae* as an instrument for advocacy, investigation and mobilisation." *Law, Democracy and Development* 2001; 5(2): 133-162. For a shorter summary of the case, see: A Kleinsmidt. Pharmaceutical Companies Abandon Case against South Africa: Victory for People with HIV/AIDS. *Canadian HIV/AIDS Policy & Law Review* 2001; 6(1/2): 75-76 (available via www.aidslaw.ca).

⁹⁶ *Grootboom v Republic of South Africa et al*, 2000 (11) BCLR 11 (CC).

care." In *Treatment Action Campaign et al v Minister of Health et al*,⁹⁷ the court ruled that by prohibiting the use of nevirapine for the prevention of mother-to-child HIV transmission outside designated pilot sites, and the absence of a comprehensive and coordinated plan for rolling out a MTCT prevention programme, the government was in breach of its constitutional duty to progressively realize the right to health care as an ongoing obligation. The court ordered the government to make nevirapine available to pregnant women with HIV who give birth using services of the public health sector and to their babies, where clinically indicated and appropriate testing and counselling is available. In addition, the court ordered the national and provincial governments "to plan an effective comprehensive national programme to prevent or reduce the mother-to-child transmission of HIV, including the provision of voluntary counselling and testing, and where appropriate, nevirapine or other appropriate medicine, and formula milk for feeding, which programme must provide for its progressive implementation to the whole of the Republic, and to implement it in a reasonable manner." Finally, the court ordered the governments to deliver a report by the end of March 2002 setting out, under oath, what steps have been taken and will be taken to implement the order regarding a national MTCT prevention plan.

Shortly afterward, government announced it would appeal the decision, arguing the courts had impermissibly entered the jurisdiction of the executive in determining national policy. At the end of January 2002, the TAC applied for an interim order that the government be compelled to comply with the ruling to make nevirapine available to pregnant women in the public sector, pending the outcome of the appeal. On 11 March 2002, the High Court granted TAC's application. The appeal was heard by the Constitutional Court in early May 2002; the decision is pending.

V. STRATEGIES FOR ADVANCING THE RIGHT TO HEALTH IN INTERNATIONAL AND DOMESTIC LAW

The preceding sections have provided a review of the status of the right to health in international law instruments, and the experience of litigating the right to health before international and domestic bodies (with a particular focus on the issue of access to medications). Making access to treatment a reality for the millions of people living with HIV/AIDS who do not yet have it obviously requires activism on many fronts. The following, final section lists some areas for possible advocacy aimed at advancing the recognition of the right to health in international or domestic law, and ensuring respect for and promotion of that right through access to treatment for people living with HIV/AIDS. Some are more feasible, others would require greater resources and be more controversial. Presented here to prompt ideas, they by no means constitute a complete list.

⁹⁷ *Treatment Action Campaign et al v Minister of Health et al*, Judgment of 14 December 2001, High Court of South Africa, Case No. 21182/2001, available via: www.tac.org.za, and summarized in: L. Gertholtz. Preventing Mother-to-Child Transmission: Landmark Decision by South African Court. *Canadian HIV/AIDS Policy & Law Review* 2002; 6(3): 1, 20-23.

(1) General advocacy within UN human rights system

There are number of avenues for NGO advocacy to advance the recognition of the right to health, and the specific dimension of access to medicines, within the UN system. These are not avenues likely to yield quick, tangible results, but should be seen as part of a longer-term advocacy project that helps build a foundation in international law for domestic law reform or litigation efforts translating those norms into enforceable entitlements.

· Special Rapporteurs

As noted above, in April 2002 the UN Commission on Human Rights unanimously agreed to the appointment of a Special Rapporteur on the Right to Health. Over the 3 years of the rapporteur's mandate, activists have an opportunity to draw the attention of the rapporteur (and through him or her the Commission on Human Rights and other areas of the UN) to ongoing barriers to access to HIV/AIDS medication, and to propose solutions to those barriers. Contributing to this "official" UN record of material on this subject creates a base for the development of other international instruments and political declarations that can be then invoked by advocates in efforts to influence States' policy and behaviour.

Other existing Special Rapporteurs with related mandates should also be approached with documentation and submissions, to the same end. For example, the two Special Rapporteurs on the impact of globalization on human rights (in particular economic, social and cultural rights) have strongly critiqued the push for strong patent rights at the expense of the right to health (with particular reference to the impact of the WTO's TRIPS Agreement, the *PMA Case* in South Africa and other recent WTO-related developments on access to HIV/AIDS medicines).⁹⁸

· Treaty-monitoring committees: reviewing country performance & developing norms

Compliance with each of the 6 major UN human rights treaties is monitored by a specialized committee of experts, which receives States' periodic reports on their compliance as well as "shadow" reports from NGOs. The committee also elaborates statements, comments and recommendations providing a non-binding, but expert, interpretation of States' obligations under the treaty, also applied in assessing States' compliance when reporting.

As noted, the Committee on Economic, Social & Cultural Rights released its General Comment 14 on the right to health in 2000; more recently, in November 2001 it adopted a statement on "human rights and intellectual property,"⁹⁹ as a preliminary step in its ongoing work to prepare a General Comment on this issue. NGOs could make submissions to the Committee as it prepares that General Comment, given the impact of strict patent regimes on access to affordable medicines.

When countries are required to submit reports (which many often do not) to various treaty-monitoring committees, treatment activists can submit "shadow reports" highlighting areas in which government (in)action is resulting in lack of access to medicines. The process itself provides an opportunity to create domestic pressure on governments, as do the potential "recommendations" or "observations" of the reviewing committee. The Committee on Economic, Social & Cultural Rights is an obvious venue, but country reports under the other treaties to other committees could also provide additional venues.

⁹⁸ J Oloka-Onyango & D Udagama. Economic, Social and Cultural Rights: Globalization and its impact on the full enjoyment of human rights. Progress report, 2 August 2001, UN Doc E/CN.4/Sub.2/2001/10.

⁹⁹ UN Doc E/C.12/2001/15.

Note that the Inter-American Commission on Human Rights and the African Commission on Human and Peoples' Rights also play a monitoring role, requesting and receiving state reports on the steps taken to comply with their human rights treaty obligations. These mechanisms provide another venue for NGO advocacy on the issue of treatment access.

Such mechanisms could be pursued by activists in both developed and developing countries, given the legal obligation under international law (eg, ICESCR, Article 2) of international cooperation to progressively realize the right to health. Activists in developed countries could highlight the actions of their own governments, for example, in other international forums (eg, the WTO) in restricting access to affordable medicines in developing countries, thereby deliberately retarding or halting the progressive realization of the right to health.¹⁰⁰

· **Political declarations**

As noted above, the Commission on Human Rights has adopted resolutions recognizing access to medications in the context of pandemics such as HIV/AIDS as a fundamental element of the right to health. Activists need to decide whether further efforts should be spent in lobbying for such resolutions, given the 2 existing ones. It may be that if/when further significant positive developments in international law are achieved in another forum (eg, the WTO, the CESC statement on IP and human rights) that these should be consolidated through having them reflected in an updated CHR resolution.

(2) Litigating in international human rights systems: complaints & communications

As noted above, the ICESCR does not provide for a mechanism for complaints to the Committee regarding breaches of the covenant. Efforts have been underway for many years to get an Optional Protocol adopted that would create a complaints mechanism. Similarly, the *Convention on the Rights of the Child* creates no complaints procedure, nor does the *Convention on the Elimination of Racial Discrimination*.

However, complaints are possible under other UN treaties and in some regional systems, offering an avenue that treatment advocates could pursue. The Optional Protocol under CEDAW¹⁰¹ has recently entered into force. It allows communications to be submitted by or on behalf of individuals or groups of individuals alleging State violation of the CEDAW. In those 40 countries which have ratified the protocol, this mechanism could be used to submit communications regarding the violation of women's right to health, including access to HIV/AIDS treatment. Similarly, under the ICCPR, an Optional Protocol ratified by 102 countries allows complaints to the Human Rights Committee. Individuals could file complaints alleging that denial of access to HIV/AIDS medications amounts to a violation of the right to life under the ICCPR, and seek a "ruling" from the Committee.

¹⁰⁰ Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights. UN Doc. E/CN.4/1987/17, Annex; *Human Rights Quarterly* 1987; 9: 122-135; *Review of the International Commission of Jurists* 1986; 37: 43-55.

¹⁰¹ Optional Protocol to the Convention on the Elimination of Discrimination against Women, UN Doc. A/54/49 (Vol. I) (2000), entered into force 22 December 2000.

As indicated above in the discussion re litigating the right to health, both the Inter-American and the African human rights systems provide mechanisms for formally raising allegations that states have breached their human rights obligations. Individuals and NGOs may lodge petitions with the Inter-American Commission on Human Rights (eg, the successful *Odir Miranda* case summarized above) alleging a breach of the Inter-American human rights instruments.

The African Commission on Human and Peoples' Rights may also examine "communications" from individuals or NGOs complaining of human rights violations, in the case of those African countries which have ratified the *African Charter on Human and Peoples' Rights*. While the Commission may only "consider" a communication if a simple majority of its members so decide (Article 55), it "shall" draw to the attention of the Assembly of Heads of State and Government any special cases relating to a "series of serious and massive violations of human and peoples' rights" disclosed by the Commission's review of one or more communications, as well as any "case of emergency duly noticed by the Commission." Given the enormous scale of the denial of access to HIV/AIDS medication in many African countries, NGO advocates could submit a communication characterizing this as a "serious or massive violation" of human rights. Such a communication would be bolstered by action such as that taken in May 2002 by the Government of Zimbabwe in declaring its HIV epidemic a "national emergency".¹⁰²

The most significant initial hurdle to pursuing such complaints is the requirement to first exhaust all remedies reasonably available under domestic law before a complaint to an international body will be found admissible. In the event of lengthy delay or effective inability to obtain a remedy from national tribunals, this requirement can be set aside.

(3) Domestic lobbying, activism, human rights education

Possible activities in this area could include the following:

- Lobby governments to report publicly and to the UN on the steps they are taking to implement Commission on Human Rights resolutions on access to medication in the context of pandemics such as HIV/AIDS. This could be undertaken by activists in both developing and developed countries, given the need for international cooperation to improve access to treatment through reforms to international trade agreements, contribution of resources for the purchase of medicines and development of healthy systems, etc. Similar efforts could be undertaken with regard to following up on the commitments made in the *Declaration of Commitment on HIV/AIDS* adopted by the UN General Assembly in June 2001.
- Undertake a "human rights audit" of national legislation relevant to accessing treatment, with particular focus on areas such as protection against discrimination, intellectual property provisions (and whether they incorporate necessary safeguards to protect public interest such as compulsory licensing, parallel importation, limits on patentability, etc), the regulation of medicines and their prices, etc.
- Prepare a document outlining the case for implementing access to treatment (including through the development of national strategies on HIV/AIDS), including identifying legal reforms or measures to be taken, and use it as a basis for engaging government officials, legislative representatives (including

¹⁰² H Cauvin. "Zimbabwe Acts to Obtain AIDS Drugs at Low Prices." *New York Times*, 31 May 2002. See additional information at: www.cptech.org/ip/health/c/zimbabwe.

representatives to regional parliaments where these exist), etc and for public education and mobilization more broadly.

- NGOs and lawyers could collaborate to organize workshops and sessions for public education on the right to health and access to medicines, and to promote activists' plans/calls for government action on treatment advocacy (such as a national treatment plan). Particular sessions could be organized to build the knowledge and activism skills of a core group of activists wanting to work on treatment access. National or local meetings could be organized to discuss and endorse an agreed-upon action plan, and could be used as an opportunity to involve a range of potential allies beyond just people living with HIV/AIDS and organizations working on HIV/AIDS.
- Activists could put together a media handbook or compilation of materials to be used in work with the media to gain coverage of treatment access issues and advocacy in an informed fashion, using the language of human rights, to counter misinformation by industry lobby groups.
- The workshops and materials described above should incorporate basic information about: human rights and its relevance/use for treatment access advocacy; key concepts in international and domestic law (eg, compulsory licensing, the WTO's TRIPS Agreement and what the Doha Declaration says, constitutional rights, how a court case proceeds, how legislation and government policy get made, etc); examples of cases where grassroots advocacy has been successful, etc.

(4) Domestic litigation

As the above survey of case law illustrates, depending on the status of international legal norms in a country's legal system and constitutional or other provisions in the law, legal action to enforce an entitlement to a right to health (and specifically access to medicines) may carry a reasonable prospect of success.¹⁰³ In addition, the paper by Berger gives examples in three different areas of law (eg, constitutional, insurance, and competition) where individuals or NGOs could initiate or intervene in proceedings to advance a claim for access to medication, bolstered by domestic and international human rights law where applicable (depending on the system of law in that country).

One idea for litigation which would directly seek to apply international human rights law, and which has the potential to attract considerable attention (regardless of its ultimate success as a law suit), would be to initiate tort litigation against private corporations or heads of state for breaches of international law under a statute such as the US *Alien Tort Claims Act*. This could be used to seek damages for specific acts resulting in, or contributing to, the denial of access to affordable medication (eg, falsely claiming a patent in a country where it has no such patent, thereby preventing the legal entry of more affordable generics; anti-competitive practices seeking to block generic competition, etc).

¹⁰³ This is more likely to be successful in legal systems (eg, in Latin America) that already establish enforceability of international law norms in/by domestic courts rather than (as in Anglo-American tradition) requiring further steps to translate international law commitments into domestically enforceable norms. International human rights norms are still important aids in litigation even in jurisdictions where they are not directly enforceable, as guides to interpretation of domestic law (eg, Canadian experience).

This US statute gives district courts "original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States."¹⁰⁴ The claim could allege such violations of international law as the rights to life and to freedom from cruel, inhuman or degrading treatment under the ICCPR or the right to health under the ICESCR or other conventions such as the CRC.

Or, more controversially, a claim could be brought alleging genocide, prohibited by both treaties and customary international law. Article II of the *Convention on the Prevention and Punishment of the Crime of Genocide* defines "genocide" as including the following acts with intent to destroy, in whole or in part, a national, ethnic, racial or religious group as such: (1) causing serious bodily or mental harm to members of the group; or (2) deliberately inflicting on the group conditions of life calculated to bring about its physical destruction in whole or in part. Note also that Article III prohibits not only genocide but also *conspiracy* to commit genocide, and *complicity* in genocide.

Any such claim would obviously face numerous legal (not to mention) political hurdles: issues of standing and representation by the individual or NGO bringing the claim; whether the alleged conduct of the corporation amounts to a "tort" in violation of international law and the scope of the human rights on which the claim is founded; whether the definition of "genocide" is satisfied, etc. But it would certainly attract attention and would let activists shape the public discussion from the outset in human rights terms.

¹⁰⁴ 28 U.S. Code § 1350. Because the statute allows for an action against an "alien" only, the defendant would have to be a corporation not resident in the US (such as a foreign subsidiary).

PAPER #2

DRUG FINANCING AND PRICE CONTROL: LEGISLATIVE INTERVENTION IN THE PUBLIC INTEREST

SHARAN PARMAR* & VIVEK DIVAN**

INTRODUCTION: HOW PRICING LAW IS USED TO PROMOTE AFFORDABILITY OF MEDICINES

The WTO's TRIPS Agreement prescribes international standards for intellectual property rights for all WTO members. Pending implementation of TRIPS in developing countries (where not already implemented) will strengthen pharmaceutical manufacturers' monopoly power, resulting in high drug prices. Legislative schemes to curb this pricing power are available, yet remain largely nonexistent in developing countries. It is important to note that TRIPS does not explicitly restrict members from controlling the prices of drugs. Health advocacy should therefore include a focus on mechanisms available whereby member countries can control the prices of drugs in order to increase accessibility and affordability, while remaining in conformity with their TRIPS commitments.

Government intervention is a necessary and common feature of the pharmaceutical market in a majority of industrialized countries, where **more than three-quarters of drug expenditure is publicly financed in some way**.¹⁰⁵ Yet the overwhelming majority of developing countries do not coordinate a comprehensive scheme of equitable ("fair") pricing. This is one factor behind reports that retail prices of some essential drugs are higher in Latin American and African countries than in industrialized ones.¹⁰⁶

It is crucial that civil society advocate for the adoption of legislative provisions that regulate drug prices in developing countries. This section on the public regulation of drug pricing seeks to introduce this topic by providing an overview of current developed and developing country legislative approaches and suggesting potential developing country options. Cooperative advocacy initiatives are strongly recommended in order to facilitate the sharing of expertise and technical knowledge on this complex subject.

Our overview aims to demonstrate the exceptional potential within coordinated lobbying efforts for responsible equitable pricing policies by answering:

- *How are drug prices determined?*
- *What schemes are employed to keep drug prices affordable in industrialized countries?*
- *What options are developing countries currently employing?*

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¹⁰⁵ S. Jacobzone, "Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goals", Labour Market and Social Policy -- Occasional Paper No. 40, Organization for Economic Development and Cooperation (OECD), April 17, 2000.

¹⁰⁶ See K. Balasubramaniam, "Is Equitable Pricing the Answer?" Health Action International News, July 2001.

- *What are the costs and benefits of current schemes and what additional issues should developing countries consider?*

I. SOCIO-ECONOMIC BACKGROUND TO DRUG PRICES

Who determines drug prices?

Retail prices usually reflect the value a consumer attaches to a product: consumers value pharmaceuticals for their therapeutic efficacy. However, pharmaceutical manufacturers enjoy a monopoly pricing power due to legislated patent protections, now applicable to all WTO members under TRIPS (although delay in implementation is contemplated under the Agreement and the recent ministerial Declaration extending the deadline for implementation with respect to pharmaceutical patents until 2016 for least-developed countries).¹⁰⁷ Under this power, "in the absence of price regulation, pharmaceutical firms will presumably charge very high prices for their on-patent drugs".¹⁰⁸ To counter this power, most industrialized countries use legislative measures to intervene in the drug market and ensure drug affordability.

Factors influencing drug pricing policy

Drug pricing policy in industrialized countries is nonetheless usually constrained by local interests in maintaining a competitive pharmaceutical industry and the drug prices of other countries. The differing emphasis placed on these concerns has resulted in the varying legislative schemes of industrialized countries.

- **Industrial interests:** Strong national price controls reduce pharmaceutical manufacturing profits and are thus argued to restrict drug innovation and hurting domestic competitiveness. This is a standard pro-industry argument, under which drug research & development (R&D) is seen as a "public good" that must be paid for through higher drug prices. However, R&D is influenced by other factors in addition to profits. More importantly, increases in profits do not necessarily translate into increased drug R&D (including the country where profit is made), because of the many factors influencing this. Proponents of equitable pricing should be aware of these weaknesses of this pro-industry argument.
- **Global Prices:** It is generally understood that drug research and development costs ought to be shared by all industrialized countries at an *international* level, through a global market for pharmaceuticals.¹⁰⁹ In some respects, a "global price-referencing" program is already taking place,

¹⁰⁷ This pricing power is cited as necessary to ensure innovation given the high R&D costs attendant to drug development. Claims by proprietary pharmaceutical companies about the level of such costs have been challenged, and without disclosure of additional inside information, should be viewed with some skepticism. Critics have also pointed to the significant percentage of drug prices attributable to advertising and promotion of brand-name pharmaceuticals, rather than R&D into products representing therapeutic advances.

¹⁰⁸ Nicholas Bloom and Jon van Reenen. "Regulating Drug Prices: Where do we go from here?" *Fiscal Studies* 1998; 19(3).

¹⁰⁹ Of note, less innovation was observed in countries where there more intense price-fixing is present. In France, for example, Jacobzone reports drug development favoured 'me-too'-type products that were established at higher prices. Likely in response to these developments, there have been recent reports of possible threats by the pharmaceutical industry to withhold innovative drugs from some European markets unless aggressive price controls are eased. Manufacturers argue that they can not rely upon price increases in less-regulated markets (such as the United States) to achieve the desired profit levels needed for drug innovation. While industry is reported to be reluctant to resort to such tactics, brand-name manufacturers are actually suggesting that European markets increase generic competition instead of relying upon such stringent price controls. See the Kaiser Daily Health Report, "European Cost Controls on Prescription Drugs Could Affect U.S. Medication Prices", June 7, 2002.

where the prices in one country influence those of another.¹¹⁰ Specifically, when setting drug prices regulators rely upon price comparisons in neighbouring countries in order to measure the reasonableness of a potential price in their own domestic market.

II. SPECIFICS OF PUBLIC INTERVENTIONS

Drug pricing policies employ demand-side and supply-side mechanisms.

- **Supply-side mechanisms** target identifiable aspects of the supply of drugs by manufacturers, such as prices, profits or costs.
- **Demand-side mechanisms** target the consumers of products, usually through public health insurance programs which reimburse or subsidize prices.

Demand-side Approaches

Demand-side regulation uses “drug financing” (also known as “cost-sharing”), which is accomplished through public health insurance schemes. In this fashion, governments use their clout as a large (usually the largest) bulk purchaser to extract lower prices from manufacturers, combined with their power to legislate the conditions of coverage. Most industrialized countries cover all or some of the drug spending of their citizens through different universal public health insurance schemes.¹¹¹ These insurance schemes operate by either fully reimbursing or subsidizing drug spending, and usually include financial incentives in order to prevent abuse.

- **Reimbursement/Subsidies:** Lists (or “formularies”) are established, which detail expenses that are eligible for reimbursement. Either the Ministry of Health or a regulatory authority usually revises these lists several times each year. National lists may allow reimbursement according to particular drugs, beneficiaries or both (see Appendix A for examples of either approach). Some governments negotiate price reductions with manufacturers who desire the listing of their drugs on public drug schemes.
- **Financial Incentives (co-payments):** Reimbursement schemes that are too generous may result in over-consumption or abuse.¹¹² To avoid this situation, drugs are not provided completely free of

¹¹⁰Jacobzone argues that the world pharmaceutical market does not necessarily consist of fragmented markets and is more unified than actually thought of. An additional potential effect of comparison pricing practice argued by Bloom and van Reenen is that lowering domestic prices will in turn affect prices in other countries, which it is claimed will lower innovation in the market generally.

¹¹¹ Coverage has fallen in recent years due to fiscal conservatism & reductions of public health expenditures. This shift has forced governments (especially European) to stabilize drug expenditure through price cuts, de-listings or lower levels of reimbursements (reported by Jacobzone). Canada, the United States and Mexico, however, do not have *universal, comprehensive* drug coverage, although in a country like Canada, a patchwork of public insurance programs are in place to provide comprehensive coverage in some circumstances (eg, all prescription medications dispensed in hospitals) or to some groups such as the elderly and the poor receiving social assistance, or to provide partial coverage for some others (eg, people with very high drug costs) under programs with deductibles geared to income.

¹¹²Self-medication is an additional concern, an instance that is argued by Jacobzone to result in greater medical expense, while others argue to the contrary (see “Encouraging Self-Medication Can Reduce the Cost Burden”, Association for the European

charge; instead, consumers pay a fixed charge that is known as a co-payment. Unfortunately, co-payments have a tendency to significantly increase over time and discriminate against people who are poor or with lower, fixed incomes. Thus, tailored safety nets are implemented, such as exemptions for the poor and chronically sick.¹¹³ (Establishing criteria for setting co-payments can be quite complex. Examples of some co-payment schemes are listed in Appendix B¹¹⁴.)

- **Drugs in Hospitals:** Coverage of drugs in hospitals is usually subject to different rules because drug costs are included in hospital budgets.¹¹⁵ Due to their size, hospitals are usually able to negotiate individual price discounts with manufacturers.

Supply-side Approaches

The scope of public insurance schemes is limited due to financial constraints. Thus, supply-side price regulation is essential in order to ensure universal access to prescription drugs, which is recognized as an important component of public health care. Supply-side regulatory tools attempt to control the monopoly power of patent-holding pharmaceutical manufacturers by targeting prices, costs¹¹⁶ or profits¹¹⁷.

Two common elements of direct price controls are “price fixing” and “reference pricing”.

- **“price fixing”:** Fixing drug prices and allowing for their free supply is a common strategy in many OECD countries,¹¹⁸ that is not without its complexities. First, determining appropriate price settings requires quite sophisticated methods. Second, due to extensive product heterogeneity (difference) amongst groups of pharmaceuticals, one price fix cannot necessarily apply to all drugs. Therefore, categories are created (with reference to such factors as therapeutic value, comparison to existing products, and prices in other countries) within which “reasonable” prices are determined and fixed.
- **“reference pricing”:** The complexities of price-fixing render it vulnerable to manipulation by market agents.¹¹⁹ In response, reference pricing is used, which bases drug prices on the actual chemical contribution of a drug and any adjustments to its quality (or efficacy). This also requires complex evaluation methods, technical expertise and their accompanying regulatory infrastructure.

Self Medication Industry (AESGP)). This is but one related issue of many that belong to overall health policy, illustrating the breadth and policy ramifications of equitable pricing strategies.

¹¹³ In the United Kingdom, for example, 50% of population is exempt from co-payments on a specific list of essential drugs.

¹¹⁴ Source: Jacobzone. For reporting of charges undertaken in the South-East Asian context, see *Financing Drugs in South-East Asia: Report of the Second Meeting of the WHO/SEARO Working Group on Drug Financing*, 1998, Ref. no. WHO/DAP/98.15 (hereinafter: *Financing Drugs in South-East Asia*).

¹¹⁵ Alternatively, Canada includes drugs (including highly specialized drugs) received in hospitals as part of hospital treatment, which is fully covered under public health care.

¹¹⁶ This approach can include “cost plus” regulation, which reimburses and controls costs while allowing a certain cost margin.

¹¹⁷ See Bloom and van Reenen’s recommendations for potential improvements to the United Kingdom’s profit controls.

¹¹⁸ Undertaken in Australia, Austria, Belgium, Finland, France, Greece, Hungary, Japan, Italy, Korea, Mexico, Norway, Spain, Sweden and Switzerland; and sometimes in Canada, Germany and the United Kingdom.

Sources: Jacobzone and the executive summary of Nicholas Bennet “Pharmaceutical Pricing Strategies 2000: Entering the New Millennium” (June 2000, Reuters Business Insights), posted on www.inpharm.com.

¹¹⁹ For example, drugs may be artificially priced too high by the manufacturer in order to circumvent the impact of price controls. Or, minor changes may be done in order to make a product appear “new”, thus enabling it to escape price controls.

III. INDUSTRIALIZED COUNTRY DRUG PRICING REGIMES

There exists a clear correlation between the extent of drug price controls and actual drug price levels in industrial countries. A study examining OECD countries found price differences to fall into the following groups:¹²⁰

- High: United States, Germany Switzerland
- Intermediate: Australia, Canada, United Kingdom (at the bottom), with the Netherlands slightly higher than the United Kingdom
- Low: Italy, Spain, Portugal, Greece and Japan, with France at the top end of this group

A glimpse of the regulatory landscape is provided in Appendix C through descriptions of the drug pricing schemes of some industrialized countries.¹²¹

IV. DEVELOPING COUNTRY INITIATIVES AND OPTIONS

The regulatory options exercised by developed countries, which we have described, are the product of intricate balances between domestic health care priorities and industry interests. However, in order to ensure equity within such an environment, "public, private and non-profit decision-makers" must "agree on ways to segment the global market so that key technology products can be sold at low cost in developing countries without destroying markets -- and industry incentives -- in industrial countries."¹²²

Therefore, current initiatives to implement equitable pricing policies in developing countries should not include wholesale adoptions of legislative models from industrialized countries. Nonetheless, the legislative pricing frameworks adopted by developing countries will *also* be the outcome of balancing competing interests. Current internal and external pressures will influence precisely where this balance is struck.

- **International pressures:** International pressures remain concerning the global sharing of drug innovation, where countries are expected to contribute according to their ability to pay. This situation is compounded by the threat that commitments to develop innovative drugs for distinctly "South" diseases may not be present if South pricing policies do not ensure strong pharmaceutical returns.
- **R&D for South Diseases:** An additional pro-industry argument warns that manufacturers' incentives to develop innovative drugs for distinctly "South" diseases may not be present if South pricing

¹²⁰Jacobzone reports that in terms of public expenditure, the lowest levels were found in Canada, the United States, Italy and Belgium; while the highest were found in Czech Republic, Luxembourg, Norway, Ireland, Spain, Germany and France. Bloom and van Reenen found similar price comparisons for a similar sample of countries with high price countries including the United States; intermediate price countries including Denmark, Germany, Netherlands, UK, Ireland; and low priced countries including Italy, France, Greece, Portugal and Spain.

¹²¹For detailed descriptions of active market interventions, including France, Italy, Netherlands, and international price comparisons, see: "International Pharmaceutical Price Differences, Research Report", Australian Productivity Commission, July 2001 (hereinafter: Australian Productivity Commission); Bennet, Bloom and van Reenem and Jacobzone.

¹²² UNDP Human Development Report 2001: *Making New Technologies Work for Human Development, 2001*.

policies do not ensure strong pharmaceutical returns. However, at present, manufacturing profits have not been especially devoted to the R&D of “innovative” drugs (drugs to treat new diseases), with a miniscule amount of actual R&D being spent towards treating tropical or poor country diseases.¹²³ Accordingly, such arguments should be rejected outright in light of past industry performance. Alternatives should be proposed, such as challenging particular manufacturers to take-on “loss leaders” for marketing purposes. Under “loss leaders”, a manufacturer voluntarily takes a profit-loss on a particular drug in return for the positive public image attendant to aiding the world’s poor or in redemption of vilified public personas earned in local industrialized markets.

- **Domestic pressures:** Individual socio-political and economic conditions will also influence the choice of options available to developing countries, especially since health policy is recognized as a distinctively domestic arena. In light of TRIPS, some developing countries may be concerned with improving local drug research and development and reluctant to impose necessary pricing constraints. As a result, health objectives will likely be weighed against internal interests in fostering an internationally competitive domestic pharmaceutical market.

Health advocacy efforts must press for regulatory choices that ensure that quality essential medicines are made affordable to a majority of the population, which are described below under potential demand and supply-side options. Our case study of Indian pricing legislation aptly illustrates how competing industrial interests can whittle away the effectiveness of price control regulation.

A. Demand-Side Options: Limited Impact of Drug Financing

State or constitutional recognition that health is a human right undoubtedly justifies public financing of drug expenditures. However, developing countries face internal issues concerning the feasibility of sustained public financing, ensuring continued availability of essential drugs and mobilizing political will for public health reform. Possible drug financing options can include:

- public finance through budget allocations;
- public health insurance schemes;
- voluntary community financing schemes;
- user charges;
- donor financing, direct donations; and
- development and commercial loans.¹²⁴

In reality, limited public funds means that drug financing alone cannot comprehensively ensure drug accessibility and affordability. This is evident from the country descriptions provided in Appendix D.¹²⁵

¹²³ “Technology is created in response to market pressures – not the needs of poor people, who have little purchasing power. Research and development, personnel and finance are concentrated in rich countries, led by global corporations and following the global market demand dominated by high-income consumers. ... As a result research neglects opportunities to develop technology for poor people. ... Of 1,223 new drugs marketed worldwide between 1975 and 1996, only 13 were developed to treat tropical diseases – and only 4 were the direct result of pharmaceutical industry research.” *Ibid* at p.3.

¹²⁴ Source: *Financing Drugs in South-East Asia*.

¹²⁵ *Ibid*.

Therefore, some form of price controls is clearly also needed, because comprehensive publicly-funded drug financing on its own is not necessarily sustainable or realistic — a reality underscored by the current reliance of most citizens of developing countries upon the private sector for their drug needs.

B. Supply-Side Options: Potential mechanisms

Drug financing in conjunction with price controls is commonplace in industrialized countries, which recognize we cannot rely upon purely market forces to ensure that health needs are being met. A comprehensive combination of equitable pricing mechanisms, such as encouragement of generic competition, use of TRIPS-compliant measures that are pro-health, and differential pricing policies have all been recommended by international NGOs active in the area of treatment access.

Supply-side strategies should focus upon sustainability and autonomy in the availability and affordability of medicines. Consideration should be made as to the best mix of the following alternatives, which are highlighted below.

Differential Pricing

“Differential pricing” takes place where manufacturers charge different prices in different countries in order to maximize revenues according to their differing market conditions. The different pricing policies of industrialized countries demonstrate their acceptance that homogenous prices for all drug products is not necessary across borders.

Developing countries have generally employed differential pricing through voluntary reductions of prices by pharmaceutical manufacturers for low-income countries. Mostly the result of price negotiations, some reductions have been successful while others more onerous because they have come attached with stringent long-term conditions that reinforce patent protections.¹²⁶ Price reduction initiatives are currently being undertaken in Africa between multinational corporations and international agencies, such as WHO, UNAIDS, UNICEF, UNDP and the World Bank. Critics say that little progress has been made through time-consuming negotiations on a country-by-country, drug-by-drug basis.¹²⁷

Brazil, on the other hand, has successfully negotiated price reductions for HIV/AIDS treatments by threatening the use of compulsory licensing of pharmaceutical products, which is permitted under Brazilian law in cases of “abusive pricing”, a national emergency, or failure to “work” a patent (ie, produce the product) in Brazil within 3 years of the patent having been granted.¹²⁸ The Brazilian experience illustrates the value of a country being able to make a credible threat to use TRIPS-compliant

¹²⁶ For an analysis of the benefits and weaknesses attached to differential pricing see Ellen’t Hoen, “Pills And Pocketbooks: Equity Pricing of Essential Medicines in Developing Countries”, adapted from a presentation at a WHO/WTO workshop in Norway, 2001.

¹²⁷ Recent action has been undertaken in Zimbabwe, where 200 people die each week from HIV/AIDS. The government has declared a national emergency, under which patent protections will be overridden in order to increase access to medicines. By introducing competition from generic products, prices for HIV/AIDS treatments are expected to plummet. Zimbabwe has also applied for a Global Fund grant and will receive funds for disease prevention and care for HIV, TB and malaria. MSF, “Zimbabwe Government Takes Emergency Action Against HIV/AIDS”, May 25, 2002, www.msf.org.

¹²⁸ For example see “Brazil Wins 49% Discount on Protease Inhibitor Viracept”, Reuters, September 5, 2001.

safeguards to offset the negative impact of strict patent rights on access to treatment for those most vulnerable.

Calls have been made for a global purchasing system through which prices may be negotiated in bulk by developing countries according to marginal costs of manufacturers.¹²⁹ Global procurement strategies may make use of economies of scale and facilitate international aid mechanisms for treatment access. Bhutan and the Maldives, as two examples, are considering bulk procurement strategies, through which cheaper prices are negotiated with manufacturers. Developing countries should nonetheless be concerned about ownership and autonomy, which should endeavour to ensure that any such system caters to domestic health needs and economic systems.

Generic Competition

The presence of generic competition permits long-term reductions in pharmaceutical prices. For example, the introduction of generic competition in markets for HIV/AIDS medications has resulted in a dramatic drop in prices in some countries and on the global market (eg, offers of triple-combination therapy from some generic manufacturers have increased pressure on proprietary companies to reduce prices of their brand-name products for developing countries). Legislative reform must be tailored in accordance with local conditions. For example, the governments of Brazil and Thailand, possessed of the domestic industrial capacity, have initiated local production of certain HIV/AIDS anti-retrovirals, leading to falling prices.¹³⁰ Where local production is not feasible, regional efforts may facilitate importing of cheaper raw materials from neighbouring sources or the parallel importing of cheaper medicines. Efforts in this regard are currently being undertaken in South East Asia.¹³¹

Domestic Price Controls

Price controls are a necessary component of drug accessibility policy, which should cover all essential drugs and maximize public health needs over industry interests.¹³² A detailed overview of a particular price control policy undertaken in India is discussed in our case study below. (For a listing of additional regulatory tools that should be considered when exploring the operation of potential price controls in the developing country context, see Appendix E.)

C. Supply-Side Options: A Case Study of Price Controls in India

The following case study from India illustrates the promise and pitfalls of pricing controls in a developing country that attempts to serve both public health and domestic industry needs.

India is a country that enjoys one of the lowest drug pricing regimes in the world largely due to its Industrial and Drug Policy and a supportive legal regime, which has, however, been whittled down over the last few years.

¹²⁹ For example see “Patient Rights Stimulate Drug Research and Development, but Do Not Help Poor Countries”, USCF News, August 2001, reporting on recommendations of USCF; VSO Position Paper at www.vso.org.uk/campaign/streetprice_summary.pdf.

¹³⁰ See “Thailand Launches World’s Cheapest AIDS Drug”, Reuters, March 2002.

¹³¹ 19th Meeting of Ministers of Health, Essential Drugs and Medicines Policy: Regional Perspective, WHO Regional Office for South-East Asia, August 2001.

¹³² Of note, however, Jacobzone found that where drug prices were fixed, as in some European countries, the presence of generic production was low.

The laws on drug manufacturing, licensing, quality control and price regulation are framed in consonance with the National Drug Policy. The legal instruments under the National Drug Policy are (1) *The Drugs & Cosmetics Act, 1940* and (2) *The Drug Price Control Order*. In addition to these laws, intellectual property protection is contained in the *Patent Act, 1970* (which recognises only process patent protection).

Historical Overview of Drug Policy & Laws in India

India's legal regime that regulates drug manufacturing, pricing, and marketing has been instrumental in India having a large and strong bulk and formulation drug¹³³ industry that has been able to provide low cost drugs. The absence of product patent protection for drugs, coupled with a strong drug policy, has facilitated the growth of the indigenous generic drug industry. In addition, the presence of a stringent price regulation mechanism has ensured low cost drug availability.

However, historically that was not the case. Prior to 1970 availability of drugs in India was mainly through imports from multinational industries. This was the period when the patent laws allowed product patents for drugs.¹³⁴

In addition to drastic changes in the patent law in 1970, in 1975 the Government appointed the Hathi Committee to inquire into the working of the pharmaceutical industry. The Committee emphasised the social utility of the industry and that there was "no justification for the drug industry charging prices and having a production pattern which is based not upon the needs of the community but on aggressive marketing tactics and created demand."¹³⁵ On the basis of the recommendations of the Hathi Committee the Government of India announced a Drug Policy in 1978.

The thrust of the Drug Policy was access to low-cost essential drugs through import substitution and developing a strong indigenous drug industry. Pursuant to the Drug Policy, 1978, the Drug Price Control Order, 1979 (DPCO) came into force.¹³⁶ This order regulated and fixed a ceiling price for a 3-tiered drug categorization including specified essential bulk and formulation drugs. A ceiling price was to be fixed for *bulk* drugs based on the company's return on net worth or capital employed. For *formulation* drugs, retail prices of controlled products were decided by applying the concept of MAPE (Maximum Allowable Post-Manufacturing Expenses), which is akin to a mark-up ex-factory cost to cover all selling and distribution costs including trade margins.

¹³³ Section 2(a) of the Drug Price Control Order, 1995: "*bulk drug*" means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards specified in the Drugs and Cosmetics Act, and which is used as such or as an ingredient in any formulation".

Section 2(h) states that: "*formulation drug*" means a medicine processed out of or containing one or more bulk drug or drugs with or without the use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals but does not include:

- (i) any medicine included in any bona fide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines;
- (ii) any medicine included in the Homoeopathic system of medicine and;
- (iii) any substance to which the provisions of the Drugs and Cosmetics Act do not apply."

¹³⁴ In 1957 the Indian Government began re-examining the patent laws the outcome of which was the Patent Act, 1970. This Act removed product patent protection on drugs and introduced a process patent regime.

¹³⁵ See Hathi Committee Report, 1975

¹³⁶ The DPCO has been framed under the Essential Commodities Act, 1955 which allows the regulation of prices of essential commodities. Drugs and medicines are listed as essential commodities.

The 1979 DPCO abandoned the distinction between an essential bulk drug included in the schedule and a bulk drug not so included (which had been made in the 1970 DPCO). Bulk drugs were, however, broadly divided into indigenously manufactured bulk drugs and imported bulk drugs.

As a consequence of the new Drug Policy and the absence of product patent protection, after the 1970's there was a boost in the growth of the Indian drug industry and a decline in imports.

The Government replaced the DPCO, 1979 with the DPCO, 1987. The changes in the DPCO essentially involved reduction of the span of price control under the earlier order, although it retained a strong monitoring system. Additionally changes were made to the laws on industrial licensing and foreign investment and a National Drug & Pharmaceutical Authority (NPPA) was established (under the *Drugs and Cosmetics Act*).

Current Regime – The DPCO, 1995

In 1994 a new Drug Policy was adopted. The thrust of the 1994 policy was to promote exports of drugs, treat the pharmaceutical industry as a high priority industry for the purpose of allowing foreign investment, and to encourage the R&D component of the industry. With all these changes, price regulation was also considerably modified. The 1994 policy carved out a path for the present DPCO, 1995 that further reduced the list of drugs to come under the purview of price regulation. The three categories of drugs included in the 1970 Order were merged into one single schedule of drugs with a uniform percentage of MAPE. Importantly the NPPA was set up, which had the expertise to fix the prices under the Order and update the list of regulated drugs. This 1994 policy was adopted against the backdrop of India becoming a member of the WTO and its obligations under the TRIPS Agreement.

The comprehensive policy and legal regime adopted from 1970 onwards was thus instrumental in (i) the growth of the local drug industry (ii) wide and low cost availability of drugs.

The shift in the Drug Policy from 1970 till date, although instrumental in the growth of strong indigenous generic drug industry and providing low-cost drugs, has undergone a change and is now posing a challenge to the prevalent “low-cost, high access” drug regime. Instead, the criterion for inclusion of drugs under price regulation has shifted from essential drugs to ensuring adequate competition for drugs of marketable “popular” use.

Under the DPCO drug manufacturers are required to disclose information that may be required by the NPPA to determine the sale price of the scheduled bulk and formulation drugs. A formula is worked out, on which basis the retail price is calculated.¹³⁷ Further for non-scheduled drugs, the Government has the power to maintain a watch on the pricing and at any point if required in public interest, may fix a ceiling price on such non-scheduled drugs.

¹³⁷ Retail Price = (Material costs + Conversion Costs + Packing materials + packing charges) + (1 + MAPE/100) + ED: See clause 7 of DPCO, 1994.

Therefore, it is crucial to review and reform the criteria for selecting drugs that come under the purview of the DPCO. The historical overview above has shown the shift in the criteria from drugs that are “need-based” to drugs of “popular use”.

The Drug Policy of 1994 has now given way to the latest Drug Policy, 2002. This drug policy continues to see the continued whittling down of drugs falling under price control. From roughly 300 drugs that were under price control in 1979 and 74 drugs in 1995, the new policy sees only 38 drugs remaining under price control, although new drugs can be added. The main criteria for imposition of drug control are¹³⁸:

- i.) Bulk drugs with annual sales of over Rs. 250 million where a single brand has market share of 50% or more, and
- ii.) Bulk drugs with annual sales between Rs. 100 – 250 million where a single brand has a market share of 90% or more.
- iii.) Additionally any drug discovered in India and patented will also be out of price control.

Issues of concern with the new drug policy and the TRIPS regime

In light of HIV/AIDS in particular and all medication in general, several issues of concern arise. Clearly, the Indian government envisages continued decrease in drug price control, contrary to its avowed goals in the 1970's of making drugs accessible to all. The argument of the pharmaceutical industry in favour of such decrease is that it will encourage investment for R&D. But the availability of anti-retroviral therapy (ART) and any new medication for HIV/AIDS is seriously jeopardised due to the WTO TRIPS Agreement and the trend being seen in India's drug policies. The change in policy from one that is need-based to one that is 'popularity-based' is cause for great concern.

Another critique of the new drug policy is that in order to circumvent the criteria for price control, corporations could easily create subsidiaries in order to ensure that no 'single brand' has market shares greater than those stipulated for price control. In this event, it may be necessary to lift the 'corporate veil' to get at the real state of a company's market position.

In light of TRIPS, certain clear concerns arise. TRIPS does not restrict WTO member nations from imposing price control on pharmaceutical products, meaning this is a legal tool open to countries to make medicines more accessible. On the other hand, the DPCO envisages price control of drugs manufactured in India only. The DPCO provides the NPPA with powers to calculate the cost of drugs manufactured in India (through MAPE), based on costs incurred locally. It does not have the wherewithal to demand that companies based abroad provide ex-factory and other expenses of manufacture in order to levy price control on them.

One interpretation of TRIPS is that it prohibits countries from requiring that a patent holder 'work' a patent locally in order to obtain rights in a country – importation would be tantamount to working of the patent.¹³⁹ Therefore, there is a strong likelihood that patent holders abroad will sell their drugs in India without being

¹³⁸ New Drug Policy, 2002

¹³⁹ This was the key issue at stake in the recent US complaint at the WTO alleging Brazil's legislation imposing such a "local working" requirement was in breach of TRIPS. While public pressure contributed to the settlement (at least for the time being) of that complaint, the issue remains unresolved.

subject to price control locally – because of TRIPS and since criteria under DPCO are insufficient to cover overseas manufacturers. The principle of automaticity would need to be applied in these circumstances – whenever a patented medicine, whether manufactured or imported is introduced or sold in the market, price control should be applied.¹⁴⁰

V. CONCLUSIONS: LESSONS LEARNED

From our discussion of regulatory mechanisms in developed countries it is clear that:

- Most drug spending in industrialized countries is reimbursed or subject to price controls.
- Existing pricing schemes are the result of compromises between domestic health and industry interests and therefore should not be wholly adopted in potential drug pricing regulatory schemes of developing countries.
- The mere presence of price control mechanisms may not necessarily be enough to achieve affordability, as witnessed in Canada or the United Kingdom, who have drug prices at levels much higher to European nations that employ stronger price controls in addition to comprehensive drug financing schemes. Care must be given to ensure that adequate price controls are in place to suit local consumers, or that insurance schemes are present for those whose needs are not met.
- The mere presence of price control mechanisms may not necessarily be enough to achieve affordability, as seen in Canada or the United Kingdom, who see drug prices at levels much higher to European nations that employ both comprehensive drug financing *and* strong price controls.
- Price controls, in particular price fixing, requires sophisticated infrastructure and expertise of regulatory administrators (such infrastructure requires legislation demanding transparency for manufacturers' pricing methods and data, which is also being called for in developed countries).
- Global pricing comparisons is proving to be a strong influence on price setting, possibly forcing some industrialized countries to restrict price controls.
- Drug financing alone can permit price discounts through negotiations with manufacturers who desire their drugs to be part of reimbursement policies (eg, see discussion of New Zealand's scheme in Appendix C), but require committed financial resources.

¹⁴⁰ Ray, Ananya, "Drug pricing: Make the Right Choice", The Economic Times, Mumbai, 1 March 2002.

From our discussion of developing country options, we can conclude that:

- Reliance upon drug financing alone achieves limited accessibility due to restricted resources; comprehensive schemes require sustainable financing that is often not available in developing countries.
- Individual country negotiations for drug discounts take time and may come with onerous conditions. Legislated automatic pricing mechanisms can better address immediate health needs without compromising country autonomy.
- Most innovative drugs are manufactured outside of developing countries. Price controls that operate through limits on costs (as employed in India) or profits may only apply to drugs produced within domestic borders. Thus, direct price controls on all products sold within the domestic market are needed -- regardless of manufacturing origin.
- Technical assistance is available from the World Health Organization and through regional information-sharing in order to implement the needed infrastructure within price control schemes (see Appendix E).
- Local and regional advocacy by health activists is imperative in order to ensure that pricing initiatives undertaken by domestic governments do not place industry interests over local health needs.

VI. FUTURE STEPS

Comprehensive drug pricing and financing strategies are used by most industrialized countries because they are necessary for the public interest. Inequities in drug accessibility between the North and South are a *global* interest that can be bettered by advocating for equity pricing schemes in developing countries that are tailored to local social and economic conditions. Since the technical characteristics and complexity of equity pricing policies lend well to cross-border cooperation, regional cooperation is a critical first step, under which technical expertise and experience-sharing may inform the creation of local schemes and build momentum for access to treatment initiatives across borders.

APPENDIX A

Reimbursement of Drug Purchases: How to set-up Reimbursement Lists

By Beneficiary

Greece: pregnant women and those with chronic disease

Korea: drug expenses from certain medical facilities

France: 100% reimbursement for the chronically ill

Canada: reimbursement only available for the elderly or social assistance recipients

By Drug Criteria

Eligibility lists are usually based upon therapeutic effectiveness. These lists require revaluation and periodic updating according to public needs and health policy.¹⁴¹ These revisions and updates permit drug substitutions once cheaper alternatives become available, thus acting as an internal check on escalating drug costs.

APPENDIX B

Supply side mechanisms:

Criteria for co-payments

- **proportionality to fixed price** (Belgium, Canada, Denmark, France, Greece, Hungary, Ireland, Korea, Luxembourg, Netherlands, Portugal, Spain, Sweden, Turkey, Switzerland & private U.S. hospital insurance)
- **fixed charge per prescription** (Austria, Australia, Germany, Japan, Netherlands, UK with mixed policies in Italy & Finland)
- **annual deductible or a stop loss** (mostly with private insurance, no reimbursement below the deductible, UK, Sweden, Netherlands, Switzerland)
- **reference pricing:** Reimbursements may also be set at the price of the lowest-available comparable drug (usually a generic). Under this form of reference pricing, the co-payment actually becomes the difference between the branded drug and public reimbursement.

¹⁴¹ For example, the Netherlands has shifted to a needs and effectiveness basis.

APPENDIX C

Developed Country Programs

New Zealand¹⁴²

Through the Pharmaceutical Management Agency (PHARMAC), a dual supply *and* demand strategy is employed. All drugs are listed on the Pharmaceutical Schedule, which specifies the price and available subsidy of a medicine. Price reductions are obtained through the subsidy *and* negotiations between manufacturers and PHARMAC, who are eager to become listed on the schedule and gain access to its market.

The schedule lists all medicines subsidized for use in community care, which may include patented and generic products. Listing criteria includes meeting population health needs, cost-effectiveness, and other available options for treatment. Reference pricing is used to set a common subsidy across sub-groups of pharmaceuticals based upon their therapeutic use. Price negotiations may be obtained by agreeing to tender only the manufacturer's drug on the list, or obtaining discounts for one in exchange for including another product on the list.

Australia¹⁴³

Australia spends approximately 15% of its public health budget on subsidizing pharmaceutical expenditures. 75% of all pharmaceuticals are eligible for subsidization under the nation's Pharmaceutical Benefits Scheme (PBS). Similar to New Zealand, once a prescription pharmaceutical wins marketing approval, its manufacturer seeks listing under the PBS, a process through which the Pharmaceutical Benefits Advisory Committee negotiates its price. Within the subsidy arrangement, Australia employs cost-containment policies that require economic evaluations and reference pricing, as is also done in New Zealand. These economic evaluations assess relative costs and health benefits of a pharmaceutical and compare them with alternatives. These comparisons permit an assessment of the reasonableness of domestic figures.¹⁴⁴

Spain¹⁴⁵

The Ministry of Health regulates the approval and pricing of pharmaceuticals. Pharmaceutical prices are kept below a national ceiling through the setting of initial drug prices and reimbursement levels according to international price comparisons, price cuts, "negative reimbursement" lists and cost containment policies. The ministry has recently encountered difficulties implementing a new reference pricing scheme and determining product groups.

¹⁴² See www.pharmac.govt.nz; Richard Brace of *Pharmac*, ed. assis. Michalis Sanidas, Norrie Thomas of LSE Health, "New Zealand: Pharmaceutical Pricing and Reimbursement policies", *Overview of Pharmaceutical Pricing and Reimbursement Regulation in Europe - Report by the London School of Economics and Social Science* Commissioned by DG Enterprise of the European Commission.

¹⁴³ See www.hic.gov.au/yourhealth/our_services/apbs.htm; and Australian Productivity Commission.

¹⁴⁴ Of interest, concerns have been raised in Australia, which has a local pharmaceutical industry of 120 companies with an annual turnover of approximately AUS\$6 billion, that the potential for low prices under the PBS may undermine investment in the Australian pharmaceutical industry. Although Australia's pharmaceutical subsidy and cost-containment mechanisms have managed to keep prices relatively low, a recent public report comparing Australian and international drug prices states that such a situation would also be affected by market forces, such as presence of skilled workers, links with educational & research institutions and domestic tax system. See Australian Productivity Commission.

¹⁴⁵ Bennet; "Spain: Pricing and Reimbursement of Pharmaceuticals", Ministry of Health Report, Commissioned by DG Enterprise of the European Commission.

Canada¹⁴⁶

Here, maximum have been established since 1987 for patented drugs, which sets a ceiling to which firms may price products and intervenes to prevent "excessive" prices. The Patented Medicine Prices Review Board fixes prices at market entry and has the power to adjust them later if necessary. The scheme has been reasonably effective in controlling the prices of patented medicines (within the legislative parameters set for it), although other factors besides pricing have allowed pharmaceutical expenditures to become the fastest growing component of health care spending in the country.

United Kingdom¹⁴⁷

Applying only to branded medicines (medicines covered by patent protection), the rules of the Pharmaceutical Price Regulation Scheme (PPRS) determine:

- a) the maximum prices that may be charged by any member to the scheme respecting health service medicines; and,
- b) the maximum profits to be made from the sale of medicines covered.

The PPRS limits the return on the capital that is invested by firms on drug development, which in essence, places a percentage limit on the profit available to be made from production facilities.

Japan

The National Health Insurance (NHI) Drug Price System also operates through a pricing and reimbursement process. Reforms are underway, however, as Japan spends a disproportionately high percentage of public health expenditure on pharmaceuticals (30% compared to the range of 13-17% in industrialized countries). The NHI sets drug prices according to a reimbursement price paid to medical institutions, which are often able to capture profits from differences between set prices paid by NHI and negotiated discounts with manufacturers.¹⁴⁸ NHI price setting criteria are quite interesting and include re-evaluating prices for drugs that have "already retrieved their investment", or "those drugs for which a difference between brands should be established", or where significant changes in market size are achieved by a product. Current reforms are being directed towards increasing the use of reference pricing.¹⁴⁹

¹⁴⁶ Of concern in this scheme is adjustments for inflation, which may result in a price cut in the event of an under-adjustment or too high a rent if an over-adjustment is made. See Jacobzone, and the PMPRB website at: www.pmprb-cepmb.gc.ca. The PMPRB 2001 Annual Report indicates that, since 1994, prices of patented drugs in Canada have remained relatively stable at levels between 5% and 12% below median international prices.

¹⁴⁷ See www.doh.gov.uk/pprs; Bennet and Bloom & Van Reenen, 1997.

¹⁴⁸ This is possible because there is no separation between prescribing and dispensing for such institutions in Japan.

¹⁴⁹ See "Japan: Pricing and Reimbursement for Pharmaceuticals", *Overview of Pharmaceutical Pricing and Reimbursement Regulation in Europe - Report by the London School of Economics and Social Science*, Commissioned by DG Enterprise of the European Commission; and Bennet.

APPENDIX D

Developing Country Mechanisms:

Examples of Current Drug Financing Initiatives and Their Limitations

Indonesia

Drugs are provided free of charge to the community through health centres (not including hospitals), where patients pay modest contributions for health care but drugs are completely subsidized. A government health insurance scheme is available to civil servants and their families. There exist no price subsidies in the private market. Accessibility has recently improved through limited state-sponsored production of pharmaceuticals.

Myanmar

Drug financing has been primarily shouldered by government revenue, whose budget allocations are limited. Trust funds have been raised in some townships that are put towards institutional development and drug purchases. User charges for selected drugs in hospitals and for essential drugs in project townships have been implemented. A reduction of commercial tax and custom duties on 76 essential drugs illustrate steps towards price control.

Nepal

The National Health Care budget allocates 30% to drug expenditure, where drugs are distributed free of charge to clients in public health facilities. Most Nepalese, however, obtain most drugs from the private sector at full price. Individual cost-sharing schemes have been initiated, such as the HMG/WHO Community Drug Supply Scheme (which tries to ensure that mostly essential drugs are purchased), the British Nepal Medical Trust that supports the Hill Drug Scheme and the Lalitpur Medical Insurance Scheme. Lack of buying capacity for low-income Nepalese and inequities in geographical distribution of drug wholesalers and retailers, through which discounts have been won by bulk purchases of hospitals, persist. A national fixed price list is needed.

APPENDIX E

Supply-side Options: Additional regulatory issues

International price comparisons are a key element used by all OECD countries in determining a "fair" pharmaceutical price in order to set accompanying price controls. Clearly, such prices may not necessarily be helpful to the developing country context. The following are snapshots of additional regulatory tools that may be required at the local or regional level in order help determine "fair" prices (in both developing and developed countries).

Transparency

Legislation requiring transparency from manufacturers on pricing information, such as price breakdowns of raw materials. This information may in turn be used to determine price controls either from a cost or profit control approach.

Databases: quality control, price comparison

As described earlier, establishing a list of medicines that are eligible for subsidies or price controls is a necessary first step to implementing price controls. The WHO Model List of Essential Drugs has been employed by some to determine such eligibility.

Creating domestic databases may permit tracking of domestic prices, while regional sharing may enable price comparisons at the regional level. For example, the Maldives has employed WHO software called SIAMED for domestic drug documenting.¹⁵⁰

Databases evaluating therapeutic benefits of cheaper comparable alternative drugs are also needed for reference pricing schemes. The WHO Certification Scheme on Quality of Pharmaceutical Products Moving in International Commerce has been suggested as a potential standard on quality and content.¹⁵¹

Rational Use

Again, treatment guidelines are needed to ensure rational use. The WHO has suggested maintaining detailed formularies to facilitate control over essential drug use.

¹⁵⁰ 19th Meeting of Ministers of Health, Essential Drugs and Medicines Policy: Regional Perspective, WHO Regional Office for South-East Asia, August 2001.

¹⁵¹ For additional assistance, see “Guiding Principles for Small Drug Regulatory Authorities, Annex 6, WHO Technical Report Series, No. 790; 35th Report of the Expert Committee on Specifications for Pharmaceutical Preparations.

PAPER #3

LITIGATION STRATEGIES TO GAIN ACCESS TO TREATMENT FOR HIV/AIDS: THE CASE OF SOUTH AFRICA'S TREATMENT ACTION CAMPAIGN

JONATHAN MICHAEL BERGER*

With an estimated 4.7 million—or approximately one-in-nine—people living with HIV/AIDS, South Africa is in crisis.¹⁵² While difficult to quantify the degree to which the epidemic will have an impact on South Africa,¹⁵³ it is generally accepted that it will result in a significant rise in morbidity and mortality,¹⁵⁴ that an increase in illness and death will have negative economic and social consequences,¹⁵⁵ and that the majority of AIDS-related deaths will be of young economically active adults.¹⁵⁶ Because a sizeable percentage of South Africa's population fall within this category of people, the HIV/AIDS epidemic has the potential to devastate social, economic, and human development.¹⁵⁷

It is also generally accepted that while the treatment of opportunistic infections may serve to delay the onset of AIDS, but for the intervention of combination antiretroviral therapy,¹⁵⁸ HIV infection results in the gradual but inevitable decline and ultimate failure of a body's immune system.¹⁵⁹ In almost all cases, only with access to antiretroviral drugs (ARVs) are people with HIV/AIDS able to lead longer and healthier lives.¹⁶⁰

It is with this understanding that South Africa's Treatment Action Campaign (TAC) was launched on 10 December 1998, International Human Rights Day. While its main objective is to campaign for the development, adoption and implementation of a comprehensive national treatment plan for people with

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¹⁵² See South Africa, Department of Health, National HIV and Syphilis Sero-Prevalence Survey of women attending Public Antenatal Clinics in South Africa 2000, ¶ 4.14, available at <http://www.doh.gov.za/docs/reports/2000/hivreport.html> (last visited Mar. 27, 2002).

¹⁵³ ALAN WHITESIDE & CLEM SUNTER, AIDS: THE CHALLENGE FOR SOUTH AFRICA 82 (Cape Town: Human & Rousseau (Pty) Ltd/Tafelberg Publishers Ltd. 2000).

¹⁵⁴ *Id.* at 81.

¹⁵⁵ *Id.* at 82.

¹⁵⁶ *Id.* at 70.

¹⁵⁷ *Id.* at 58. See also Malcolm Steinberg et al., *Chapter 15: HIV/AIDS – facts, figures and the future*, in ANTOINETTE NTULI ET AL., EDS., SOUTH AFRICAN HEALTH REVIEW 2000 (Durban: Health Systems Trust, 2001), available at <http://www.hst.org.za/sahr/2000> (last visited Mar. 27, 2002).

¹⁵⁸ Antiretroviral drugs, drugs that specifically target HIV infection itself rather than the opportunistic infections that are associated with HIV/AIDS, are combined in various different treatment regimens that collectively are known as highly active antiretroviral therapy or HAART. DARRELL E. WARD, THE AMFAR AIDS HANDBOOK: THE COMPLETE GUIDE TO UNDERSTANDING HIV AND AIDS 68-69 (1999).

¹⁵⁹ *Id.*

¹⁶⁰ Approximately five per cent of all people with HIV have survived for more than 10-12 years without antiretroviral treatment and without showing signs of HIV infection. *Id.* at 77.

HIV/AIDS, TAC also works towards the prevention and elimination of new HIV infections and to improve the accessibility and quality of health-care services for all.¹⁶¹

The first of many obstacles that stands in the way of ensuring access to treatment for HIV/AIDS is the absence of a sustainable supply of affordable ARVs. While local and international pressure has resulted in significant price reductions, ARVs still remain too expensive. TAC believes that only through the introduction of generic competition will prices drop to affordable levels and supplies remain sustainable. This understanding explains TAC's opposition to drug donations and price reductions that have the effect of preventing the market entry of generic competition.

A further challenge faced by TAC is ensuring that the private health care sector provides treatment for those who have medical insurance. While medical schemes are statutorily required to provide minimum benefits to people with HIV/AIDS, they are not yet required to provide benefits that extend beyond the treatment of opportunistic infections and hospitalisation.¹⁶² The extent of the HIV/AIDS epidemic and the relationship between the public and private sectors in South Africa means that treatment for the majority of South Africans is to some extent dependant on the medical insurance industry being able to carry its share of the load.¹⁶³

TAC's greatest challenge is in ensuring that the public health care sector provides comprehensive treatment to the majority of people who do not have or are unable to afford medical insurance and are therefore reliant on the state. However, not only is there a glaring lack of political will to implement a treatment plan, but until fairly recently national government had embarked on what seemed to be a deliberate strategy consciously to misrepresent the issues and thereby create confusion, what one political commentator characterised as a commitment "to a comprehensive roll-out of obfuscation."¹⁶⁴ In addition, the state had sought to vilify civil society and generally to present every challenge as an insurmountable obstacle.¹⁶⁵ Nevertheless, TAC's starting point remains that the public health care system can, should and is constitutionally obliged to develop and implement a comprehensive national treatment plan, which includes the use of ARVs where medically indicated. Quite clearly, a national treatment plan is dependant on government making resources available for the strengthening and development of health care infrastructure. Our courts have held that proper planning is central to the marshalling of resources required for the implementation of such programmes. In *Treatment Action Campaign and Others v. Minister of Health and Others*, the Pretoria High Court held that "[o]nly if there is a coherent plan will it be possible to obtain the further resources that are required for a nationwide programme [to reduce the

¹⁶¹ TAC's programme of action also includes promoting treatment awareness and treatment literacy; campaigning for the use of ARVs to prevent mother-to-child transmission of HIV; campaigning against profiteering by drug companies; building networks and alliances with trade unions, employers, religious bodies, women and youth organisations, lesbian and gay organisations and other interested sections of the community; and maintaining pressure on national and provincial governments to fulfil their constitutional obligations towards people with HIV/AIDS. See Treatment Action Campaign, at <http://www.tac.org.za/about.htm> (last visited Mar. 27, 2002).

¹⁶² Annexure A and regulations 8 and 9 of the Regulations in Terms of the Medical Schemes Act, 1998 (Act No. 131 of 1998), *Government Gazette* 6652, GN R1262 (Oct. 20, 1999).

¹⁶³ See *The Pharmaceutical Manufacturers' Association v. The President of the Republic of South Africa*, case no: 4183/98, High Court of South Africa (Transvaal Provincial Division) (March 2001), unreported case available at <http://www.tac.org.za/Documents/MedicineActCourtCase/affiavd.doc> (last visited Apr. 8, 2002) (Affidavit of Alexander Marius van den Heever).

¹⁶⁴ Jonathan Shapiro (Zapiro), *A mixed message from government*, SUNDAY TIMES, FEB. 24, 2002, available at <http://www.sundaytimes.co.za/2002/02/24/insight/zap.gif> (last visited Mar. 4, 2002).

¹⁶⁵ See, e.g., National Executive Committee of the African National Congress, *Lend a Caring Hand of Hope*, available at <http://www.anc.org.za/ancdocs/pr/2002/pr0320a.html> (last visited Mar. 27, 2002); But see Cabinet Statement on HIV/AIDS, Apr. 17, 2002, available at <http://www.gov.za/speeches/cabinet/aid02.htm> (last visited Apr. 18, 2002).

transmission of HIV from mother to child], whether in the form of a reorganisation of priorities or by means of further budgetary allocations.”¹⁶⁶

I. THE ROLE OF LITIGATION

In a letter written in 1905 to jailed comrades, Lenin recommended that they participate in their trial only if it could be used for political agitation. If this was not possible, they were advised to remain silent. On the role of “the most reactionary people”—also known as lawyers—Lenin was less encouraging. Writing of the need to rule them “with an iron rod and put them in a state of siege, for this intelligentsia scum often plays dirty,” his advice was simple: “It’s better to fear lawyers and not trust them”.¹⁶⁷

In South Africa, however, our approach is somewhat different. Our fine tradition of public interest litigation illustrates how law may effectively be used in support of larger human rights struggles.¹⁶⁸ “Because the [South African] regime used legal institutions to construct and administer apartheid”, Richard Abel explains, “it was vulnerable to legal contestation.”¹⁶⁹ As E.P. Thompson notes, “[t]he essential precondition for the effectiveness of law, in its function as ideology, is that it shall display an independence from gross manipulation and shall seem to be just. It cannot seem to be so without upholding its own logic and criteria of equity; indeed, on occasion by actually being just.”¹⁷⁰

Democratic South Africa is a fundamentally different place. While the distinguishing feature of public interest litigation in the apartheid era was the attempt to control the exercise of public power and thereby limit and reduce human rights violations, TAC’s use of the law in securing access to treatment is to ensure—rather than prevent—state action. But while TAC recognises that public interest litigation may be used as an important tool of social change, it also believes that the use of law should be limited and strategic, that the lawyer plays an important albeit limited role within a broader social movement, and that a comprehensive understanding of the political and economic context informs the manner in which the law is used to further the aims of the movement.

¹⁶⁶ TAC v. Minister of Health, 2002 (4) BCLR 356 (T). See also Mitch Besser et al., *Interim Findings on the national PMTCT Pilot Sites: Lessons and Recommendations*, iv-v, at <http://www.hst.org.za/pubs/pmtct/pmtctinterim.htm> (last visited Mar. 4, 2002). A government commissioned study of its limited prevention of mother-to-child transmission (PMTCT) programme made the following recommendations:

Plans for expansion must therefore simultaneously address the systemic and infra-structural constraints in order to avoid a multiplication of poor and/or non-sustained service delivery, as well as to reduce levels of health care inequity. As with other services, the full potential of the PMTCT programme to reduce the number of HIV infected babies and improve overall health status will only be realized if the health system is capable of delivering the service optimally.... It would be more useful to highlight the potential of the PMTCT programme to act as an engine or catalyst for the improvement of the health system and of primary health care services in general.... Failing to conceptualize the PMTCT programme in this broader and catalytic role could represent a missed opportunity for the country, or even worse, result in the PMTCT programme undermining other essential areas of primary health care.

¹⁶⁷ See PLONOE SOBRANIE SOCHINENII (5th ed. 1958-1965), cited in Jane Burbank, *Lenin and the Law in Revolutionary Russia*, 54 SLAVIC REV. 23, 29-30 (1995).

¹⁶⁸ See RICHARD L. ABEL, *POLITICS BY OTHER MEANS: LAW IN THE STRUGGLE AGAINST APARTHEID, 1980-1994* at X-XI (1995) (Forward by Geoffrey Budlender).

¹⁶⁹ *Id.* at 3.

¹⁷⁰ E.P. THOMPSON, *WHIGS AND HUNTERS: THE ORIGIN OF THE BLACK ACT* 262-63 (1975).

As a result, TAC's approach to the use of law is multifaceted. While TAC aims to secure a legal victory whenever litigation is undertaken, the organisation is also highly aware of the role of the litigation process beyond the orders made in court judgments. In addition, by framing political and moral demands in the language of legal rights and constitutional obligations, TAC seeks to use the law without necessarily having to litigate. Recognising that the "formal content of a bill of rights is often less useful than the fact that it brings under scrutiny the justification of laws and decisions",¹⁷¹ Etienne Mureinik provides the basis for such an understanding:

"[A]ny decisionmaker who is aware in advance of the risk of being required to justify a decision will always consider it more closely than if there were no risk. A decisionmaker alive to that risk is under pressure consciously to consider and meet all the objections, consciously to consider and thoughtfully to discard all the alternatives, to the decision contemplated. And if in court the government could not offer a plausible justification for the programme that it had chosen ... then the programme would have to be struck down.... The knowledge that any government programme could be summoned into court for searching scrutiny would force its authors closely to articulate their reasons for dismissing the objections and the alternatives to the programme, and precisely to articulate the reasons that link evidence to decision, premises to conclusion. The need to articulate those reasons during decisionmaking would expose weaknesses in the programme that might force reconsideration long before the need arose for judicial challenge."¹⁷²

Litigation is also used to place issues on the agenda, both before the judge and in the court of public opinion. In the much-publicised case of *The Pharmaceutical Manufacturers' Association of South Africa and Others v. The President of the Republic of South Africa and Others*,¹⁷³ one of TAC's primary objectives was to "turn a dry legal contest into a matter about human lives", not only for the purpose of placing the impugned legislation in its proper context but also to influence public opinion.¹⁷⁴ Thus TAC's founding affidavit was deposited by the campaigns co-ordinator of the Congress of South African Trade Unions (COSATU),¹⁷⁵ South Africa's largest trade union federation and a partner in the ruling African National Congress-led tripartite alliance government,¹⁷⁶ with supporting affidavits from people living with HIV/AIDS and doctors offering "personal testimony about living with HIV or AIDS in the shadow of medicines that are available but not affordable."¹⁷⁷

II. LITIGATION PRIORITIES FOR 2002

TAC's litigation strategy for this year is an integral part of its broader campaign for the development, adoption and implementation of a public sector national HIV/AIDS treatment plan. As part of this campaign, TAC is co-hosting a national HIV/AIDS treatment conference with COSATU in June,

¹⁷¹ Etienne Mureinik, *Beyond a Charter of Luxuries: Economic Rights in the Constitution*, 8 S. AFR. J. HUM. RTS. 464, 471 (1992).

¹⁷² *Id.* at 471-473.

¹⁷³ See *The Pharmaceutical Manufacturers' Association v. The President of the Republic of South Africa*, *supra* note 12.

¹⁷⁴ Mark Heywood, *Debunking 'Conglomo-talk': A Case Study of the Amicus Curiae as an Instrument for Advocacy, Investigation and Mobilisation* 12 (paper on file with author) (presented at *Health, Law and Human Rights: Exploring the Connections—An International Cross-Disciplinary Conference Honoring Jonathan M. Mann*, Philadelphia, PA, Sept. 29 – Oct. 1, 2001).

¹⁷⁵ Ms. Theo Steele, also an executive member of TAC.

¹⁷⁶ The third member of this alliance is the South African Communist Party.

¹⁷⁷ Heywood, *supra* note 1746.

and is currently completing its research on the financial implications of a national treatment plan and the economic and social benefits of treating people living with HIV/AIDS with appropriate medicines.¹⁷⁸

TAC is focusing on three areas of litigation this year: the conclusion of the prevention of mother-to-child transmission of HIV (PMTCT) case, a complaint before the Competition Commission on excessive pricing of brand-name ARVs and refusals to grant voluntary licenses, and a constitutional challenge to the limited coverage for people with HIV/AIDS offered by the country's largest health care insurer. Together, these cases target the three identified obstacles to treatment—government, the brand-name pharmaceutical industry and the health care insurance industry. In so doing, TAC maintains its independence and ensures that its opposition to various government policies is based on the principle of identifying and challenging obstacles to treatment access wherever they exist, but that it is prepared to fight alongside government wherever and whenever they “do the right thing”. As TAC Chairperson Zackie Achmat described the relationship between his organisation and the government after the brand-name industry withdrew its case against government in April 2001: “Our alliance with the government is not over.... As in any marriage we are the foremost supporters when necessary and the staunchest critics when necessary.”¹⁷⁹

A. PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV (PMTCT)

At its launch on 10 December 1998, TAC called for the introduction of a national PMTCT programme. Calling on government to “plan for resources to introduce free AZT for pregnant mothers with HIV/AIDS”, TAC also made the first call on government “to develop a comprehensive and affordable treatment plan for all people living with HIV/AIDS.”¹⁸⁰ Just over three years and hundreds of thousands of preventable paediatric HIV infections later, TAC's position was vindicated by a High Court judgment ordering government to provide the antiretroviral drug nevirapine where public health facilities have the capacity to do so and to plan the phased rollout of a comprehensive national PMTCT programme to those areas where capacity does not yet exist.

Since the decision of the Pretoria High Court on 14 December 2001, a number of significant developments have taken place. Exactly one month later, KwaZulu-Natal Premier Mtshali announced that his provincial government had adopted the “principled decision” that it is “under obligation to supply anti-retroviral drugs to pregnant mothers who are HIV-positive”.¹⁸¹ In his opening address to the provincial legislature the following month, Mtshali made the following announcement:

“On Monday 21 January 2002, I issued a media statement wherein I took a principled position that the government of this Province is under an obligation to supply anti-retroviral drugs to pregnant mothers who are HIV positive. In this regard, I have formally accepted the free donation of Nevirapine from Boehringer Ingelheim for five years....

¹⁷⁸ The campaign for expanded access to antiretroviral therapy is based on the principles set out in the Bredell Consensus Statement, adopted at a conference hosted by TAC on 18-19 November 2001, Treatment Action Campaign, *available at* www.tac.org.za/Documents/Statements/bredell3.pdf (last visited Mar. 4, 2002).

¹⁷⁹ Nicol Degli Innocenti & David Pilling, *South Africa's Positive Force*, FT.COM, Apr. 20, 2001, *available at* <http://news.ft.com/ft/gx.cgi/ftc?pagename=View&c=Article&cid=FT300MG9SLC&live=true> (last visited May 7, 2002).

¹⁸⁰ HIV/AIDS Treatment Action Campaign Press Release (Dec. 10, 1998), AIDS Law Project, *available at* <http://www.hri.ca/partners/alp/press/treat.shtml> (last visited Mar. 4, 2002).

¹⁸¹ *KZN Moves to Save Its' Babies From Aids*, MAIL & GUARDIAN, Jan. 22, 2002, *available at* <http://www.mg.co.za/mg/za/archive/2002jan/22jan-news.html#save> (last visited Mar. 4, 2002).

As a Premier who heads a legitimate government, I must ask myself, as our posterity will undoubtedly do, what went wrong in South Africa for a judge to have to order us to have a plan and re-prioritise in order to save our children. Certainly, history will judge us harshly for the appealing of this ruling and the many unfounded attacks made on it on the grounds that it threatens to interfere in government policy-making.

I am pleased to announce that our Department of Health has submitted to Cabinet a plan for the roll-out province wide, of the MTCT programme. Cabinet of course adopted this with the proviso that the time frames be brought forward. We agreed that the public institutions and doctors that are ready to prescribe nevirapine must go ahead. We also agreed to re-prioritise and allocate more resources to this programme. This is what is required if we are to do justice to the exigency of the case. I will not have another 20,000 HIV positive children who could have been saved on my conscience in 2002.”¹⁸²

A week earlier, Gauteng became the first wholly African National Congress-controlled provincial government to commit itself to the full rollout of a similar programme. During his opening address to the provincial legislature, Gauteng Premier Shilowa committed his government as follows:

“During the next financial year, we will ensure that all public hospitals and our large community health centres provide Nevirapine for the prevention of mother to child transmission.

Within the next 100 days we will launch the programme at Pretoria Academic, Heidelberg, Dr Yusuf Dadoo, Far East Rand, Pholosong, Tembisa, Tambo Memorial and Edenvale hospitals. This will be in addition to the Garankuwa/Soshanguve complex which will be launched by 22 February 2002.

Our long-term objective is, to make it possible for pregnant women throughout Gauteng to access the full package of care within a reasonable distance from their homes. An amount of R30 million will be made available to back our words with action.”¹⁸³

While the three most influential provinces are already giving effect to the substance of the December judgment, a number of other provinces have also signalled an intention to expand their programmes. Addressing the opening of the Limpopo provincial legislature on 14 February 2002, for example, Premier Ramatlodi stated that his government is “examining the possibility of expanding the [PMTCT] trials to other institutions, particularly to ... [their] six major district hospitals.”¹⁸⁴ In addition,

¹⁸² Premier LPHM Mtshali, State of the Province Address (Feb. 25, 2002), *available at* http://www.kwazulu.net/Premier/ff_premier.htm (last visited Mar. 4, 2002). In his address, Mtshali indirectly attacked President Thabo Mbeki’s HIV denialist position as follows: “HIV causes AIDS. In this Province this axiom of science is not open to bizarre personal theories with no relation to reality.” *Id.*

¹⁸³ Address by Premier Mbhazima Shilowa at the opening of the Gauteng provincial legislature (Feb. 18, 2002), *available at* <http://www.gpg.gov.za/docs/index-pr.html> (last visited Mar. 4, 2002).

¹⁸⁴ Fourth Address to the Second Legislature of the Northern Province (2002) by the Premier Adv. Ngoako Ramatlodi, *available at* <http://www.northern-province.gov.za/docs/prsp.html> (last visited Mar. 5, 2002). *But see Limpopo province won't adhere to Nevirapine ruling*, SABC NEWS, *available at* <http://www.sabcnews.com/politics/government/0,1009,30955,00.html> (last visited Mar. 25, 2002) (where the member of the Executive Council (MEC) of the Limpopo Provincial Government responsible for health stated that his department will not expand the programme beyond the two existing research sites in the province). *See also* Eastern Cape Provincial Government State of the Province Address by the Premier of the Province of the Eastern Cape, Rev. M.A. Stofile at the Provincial Legislature Chamber, Bisho (Feb. 15, 2002), *available at* <http://www.ecprov.gov.za/speeches/premier/2002/address.htm> (last visited Mar. 5, 2002). Some provinces, however, will

a government commissioned study came to the conclusion that “[t]here are no good reasons for delaying a phased expansion of PMTCT services in all provinces.... The systemic weaknesses and infra-structural constraints identified by this evaluation are not reasons for delaying action, but are important for informing the planning and expansion of PMTCT services.”¹⁸⁵

The significance of these developments is heightened when one considers the situation that existed in the ten months prior to the launch of the litigation, a state of affairs often characterised by inertia and deliberate delay in which doctors and other health care workers were hamstrung by officialdom, remaining largely silent. As late as 24 October 2000, a day before the Joint United Nations Programme on HIV/AIDS (UNAIDS) recommended that PMTCT programmes constitute a base level of care for pregnant women with HIV and their children,¹⁸⁶ the Minister of Health stated that “[t]here is a narrow view again that continues to associate prevention of mother to child transmission of HIV with the use of antiretrovirals only.... We know there are other medical interventions.... We know ... [antiretrovirals] are toxic.”¹⁸⁷

Nevertheless, a decision to implement a pilot programme was taken by the national government a couple of months later at the end of 2000.¹⁸⁸ Implementation was irregular and erratic. While the Guguletu site in the Western Cape was up and running by January 2001,¹⁸⁹ implementation in Durban took an additional five months,¹⁹⁰ with the Rustenburg Hospital only starting to provide PMTCT services in December 2001.¹⁹¹ Legitimate obstacles and constraints only go some of the way in explaining why implementation in many sites only began in the latter half of 2001,¹⁹² after TAC instituted legal proceedings in the Pretoria High Court in August 2001.

While recent developments on the ground offer hope, government has continued to play its delaying game. On 1 March 2002, TAC was forced to bring an application before the Pretoria High Court for leave to execute part of the order made by that court in December, as government’s notice of intention to appeal the matter to the Constitutional Court had effectively put the original order on ice. The application to execute deals with that part of the order permitting doctors in the public sector to prescribe nevirapine outside of pilot sites where capacity to do the requisite testing and counselling exists, and requires of government to make nevirapine available at such facilities.¹⁹³

not expand their programmes until told to do so by the national government. See, eg., *Mpumalanga stands firm on which hospitals can provide drugs*, DAILY MAIL & GUARDIAN, available at <http://www.mg.co.za/mg/za/archive/2002feb/features/25feb-mpumalanga.html> (last visited Mar. 5, 2002).

¹⁸⁵ Besser et al., *supra* note 1668, at iv.

¹⁸⁶ Press Release, UNAIDS, Preventing Mother-to-Child HIV Transmission: Technical Experts recommend Use of Antiretroviral Regimens Beyond Pilot Projects (Oct. 25, 2000), available at <http://www.unaids.org/whatsnew/press/eng/geneva251000.html> (last visited Oct. 25, 2000).

¹⁸⁷ Steven Swindells, *South Africa Limits Role of Key Drugs in AIDS Fight* (Oct. 24, 2000), at <http://www.aegis.com/news/re/2000/RE001017.html> (last visited Mar. 6, 2002).

¹⁸⁸ Besser et al., *supra* note 1668, at 1.

¹⁸⁹ This site includes the Guguletu Midwife Obstetric Unit and eight clinics in the Nyanga district. *Id.* at 6.

¹⁹⁰ The Durban site includes King Edward VII Hospital and Kwamashu Polyclinic, and Prince Mysheni Hospital and feeder clinics in section D and K, Umlazi. *Id.* at 7.

¹⁹¹ The Rustenburg Hospital is part of the Thlabane site in the North West Province. *Id.*

¹⁹² *Id.* at 3.

¹⁹³ At the same time, the state made a successful application in terms of the Constitutional Court Rules, 1998, for Judge Botha to certify “that it is in the interests of justice for the matter to be brought directly to the Constitutional Court and that there is reason to believe that the Court may give leave to the appellant to note an appeal against the decision on such matter.” Constitutional Court Rule 18(2) (1998), GOVERNMENT GAZETTE 18944, GN R 757 (May 29, 1998). The application for a certificate in terms of these rules precedes the application for leave to appeal, which is sought directly from the Constitutional Court.

The test for leave to execute is based on considerations of justice and equity, with the court having “a wide general discretion to grant or refuse leave, and, if leave be granted, to determine the conditions upon which the right to execute shall be exercised”.¹⁹⁴ Central to the court’s discretion is the “potentiality of irreparable harm or prejudice” to either appellant or respondent,¹⁹⁵ with the court’s discretion having to be exercised in the light of constitutional rights.¹⁹⁶ In this case, rights to life, dignity, freedom and security of the person and access to health care services are central to the exercise of discretion. On 11 March 2002, TAC’s application for leave to execute was granted.

A few days later, government took the matter back to court in an attempt to appeal the order to execute. In his judgment of 25 March 2002, Justice Botha refused to certify that the interests of justice demand that the execution order be brought directly to the Constitutional Court on appeal, stating as follows:

“I am also not convinced that another court will find that I have exercised my discretion incorrectly. In essence I had to balance the loss of lives against prejudice that could never amount to more than inconvenience. I find it unlikely that another court will conclude that the choice that I made was wrong.... In the end the choice was between tolerating the loss of life and tolerating inconvenience, no matter how many lives were at stake. I do not think that there is a reasonable prospect that another court will find that I exercised my discretion injudicially.”¹⁹⁷

Nevertheless, government approached the Constitutional Court directly. Despite being in recess, the Court heard the application for leave to appeal the execution order on 3 April 2002. Without giving any reasons, a unanimous bench of 11 judges dismissed the application the following day.¹⁹⁸ In its ruling, the Court states that the “order obliges government immediately to comply with paragraph 2 of the order made by the High Court on 14 December 2001”, and that “[i]t will apply until this Court gives judgment in the main proceedings to be heard on 2 and 3 May 2002.”¹⁹⁹ The Court continued:

“As Botha J made clear in his judgments, this order does not require the wholesale extension of the prescription of Nevirapine outside the pilot sites established by the government. It requires only that government make Nevirapine available in public health facilities where in the opinion of the attending medical practitioner in consultation with the medical superintendent of a clinic or hospital, it is medically indicated and the preconditions for its prescription already exist.”

The application for leave to appeal against Justice Botha’s original judgment was argued in the Constitutional Court in early May 2002. In directions issued to the parties, Chief Justice Arthur Chaskalson instructed the parties to deal with both the application for leave to appeal and the merits of the application itself “so that the matter can be disposed of without hearing further argument if leave to

¹⁹⁴ South Cape Corporation (Pty) Ltd v Engineering Management Services (Pty) Ltd, 1977 (3) SA 534, 545 C-G (A).

¹⁹⁵ *Id.*

¹⁹⁶ See Investigating Directorate: Serious Economic Offences v. Hyundai Motor Distributors (Pty) Ltd.; In re: Hyundai Motor Distributors (Pty) Ltd v. Smit NO, 2001 (1) SA 545 (CC), 2000 (10) BCLR 1079 (CC), ¶¶ 38-40.

¹⁹⁷ See Treatment Action Campaign and Others v. Minister of Health and Others, unreported judgment of the High Court of South Africa, (Transvaal Provincial Division), case no: 21182/2001 (Mar. 25, 2002) (judgment on file with author).

¹⁹⁸ See Minister of Health and Others v. Treatment Action Campaign and Others, unreported order of the Constitutional Court of South Africa (case no: CCT 9/02) (Apr. 4, 2002), available at <http://www.concourt.gov.za/cases/2002/tac2sum.shtml> (last visited Apr. 4, 2002). This order states that “[r]easons ... will be furnished in the Court’s judgment in the main proceedings.” *Id.* ¶ 6.

¹⁹⁹ *Id.*

appeal is granted.”²⁰⁰ The matter should finally be resolved by June 2002, although there is no guarantee that judgment will be delivered so soon.

At issue in the appeal is the extent to which a court may review policy decisions of the state. In essence, the state is arguing that by ordering it to provide nevirapine where capacity for its administration exists and demanding that it produce a comprehensive plan for a national PMTCT programme, the High Court has made policy and thereby infringed the separation of powers doctrine. TAC’s response to this deliberate misrepresentation of the judgment is that it does nothing more than determine that the policy choice already made by government violates constitutionally entrenched rights, including the rights to life, dignity, bodily and psychological integrity and access to health care services.

The PMTCT case is not just about good facts and better legal argument. TAC’s public campaign which preceded and has accompanied the litigation has not only managed to achieve what South Africans term “sufficient consensus” on the issue, but has also provided space for public debate on the state’s HIV/AIDS policies. The campaign—of which the litigation is an integral part—has created the conditions for provinces like Gauteng and KwaZulu-Natal to expand their programmes. Such actions clearly undermine the arguments put forward by the state that planning for a rollout before the pilot sites have completed their work is premature. In addition, high levels of sustained public pressure have served to mobilise key constituencies such as health workers, scientific researchers and their representative bodies.²⁰¹ Such persons often provide the courts with the requisite expert evidence necessary for the resolution of legal matters. Even government’s policy on the matter has shifted fundamentally, first with the introduction of the pilot sites, and recently with a commitment in an affidavit filed before court that they “have always maintained that they intend to roll out the programme of making Nevirapine available at all public health facilities”.²⁰² Despite the doublespeak of official discourse, and regardless of the outcome of the appeal, the rollout of a comprehensive national PMTCT programme is clearly on the cards.

B. REDUCING THE PRICES OF ESSENTIAL MEDICINES

In spite of the many price reductions on ARVs that occurred in 2001, these medicines remain exorbitantly priced and, therefore, unaffordable for sustained and widespread use in a developing country such as South Africa. Believing that generic competition in the market for essential medicines is central to the reduction of prices, TAC is examining various legal strategies to obtain compulsory licences on

²⁰⁰ See Constitutional Court of South Africa, Directions of the Chief Justice, available at <http://www.concourt.gov.za/directions.html#> (last visited Mar. 27, 2002).

²⁰¹ See, e.g., Southern Africa Documentation and Cooperation Centre, *South Africa: Doctors Defy Ban on Anti-retroviral Drugs*, at <http://www.sadocc.at/news/2002-018.shtml> (last visited Mar. 5, 2002). The South African Medical Association (SAMA) is quoted as follows:

The Human Rights, Law and Ethics Committee of SAMA affirms its strong support for the rights of medical practitioners to clinical independence and autonomy.... This includes the right to treat patients without undue influence, pressure or victimisation from employers or government institutions.... SAMA also supports the rights of patients to receive necessary treatment, always with their informed consent. This includes the rights of all pregnant women who are HIV positive to receive the best available treatment that has been proven to reduce mother to child transmission.

Id.

²⁰² Applicants’ Heads of Argument on Leave to Appeal and Application to Execute ¶ 3.3, available at <http://www.tac.org.za/Documents/MTCTCourtCase/Head-mtct-1-march-2002.doc> (last visited May 6, 2002) (quote by Dr. Ayanda Ntsaluba, Director-General of Health, in his answering affidavit on behalf of the respondents in the application for leave to execute against part of the original order in the main case). See also Cabinet Statement on HIV/AIDs, *supra* note 14.

essential medicines, as well as beginning campaign and legal work for a drastic reduction in the prices of essential diagnostic tools needed for the management of HIV.

In October 2001, Cipla–Medpro (Pty) Ltd (Cipla) lodged a complaint with the South African Competition Commission alleging that certain brand-name pharmaceutical companies have abused their dominant positions in the market by engaging in excessive pricing of their products and entering into certain exclusionary licensing and/or agency arrangements, in violation of legal restrictions on vertical and horizontal market arrangements.²⁰³ In essence, Cipla wants to be granted compulsory licenses to import and market generic ARVs.²⁰⁴ The branded versions of these drugs are currently under patent in South Africa, with compulsory licenses yet to be issued.

TAC has decided to intervene in the matter by placing its own complaint before the Competition Commission. With a focus on excessive pricing and refusals to grant licenses, TAC believes that its' complaint will—at minimum—result in a thorough investigation of pricing practices. But a successful complaint could lead to a declaration that a brand-name company has engaged in prohibited excessive pricing and/or a refusal to grant licenses, as well as an order compelling such a company to lower the prices of the ARVs in question to non-excessive amounts and/or to grant licenses. In addition, a successful complaint could lead to the imposition of a substantial administrative penalty.²⁰⁵

TAC has decided to pursue the competition law avenue at this stage for a number of reasons. First, the Competition Commission is already investigating the complaint submitted by Cipla. TAC is concerned that this investigation is taking place in the absence of a public campaign on the issue. Of further concern is Cipla's failure to deal with broader issues of public interest. These shortcomings not only have the potential to limit the benefit of any successful challenge, but also serve to keep the matter out of the public domain. Without broader debate, there is every incentive for the brand-name companies to drag legal processes out for as long as possible, in the hope that Cipla may eventually settle on substantially less favourable terms than originally requested.²⁰⁶ TAC's intervention will force such companies to reconsider any protracted legal action if they are to avoid the type of public relations disaster that accompanied the *Pharmaceutical Manufacturers' Association* case.²⁰⁷

Second, as a regulator with broad powers of investigation, the Commission is able to conduct an independent investigation into drug pricing. As part of its work, the Commission will be asked to deal with the actual costs of research and development in its determination of whether the prices charged for ARVs bear a "reasonable relation" to their "economic value",²⁰⁸ particularly in respect of those drugs that were developed using public funds.²⁰⁹

²⁰³ Cipla-Medpro (Pty) Ltd is a joint venture between Cipla Ltd, an Indian generic pharmaceutical company, and its South African partner, Medpro Pharmaceutica.

²⁰⁴ AZT, 3TC, nevirapine and AZT/3TC.

²⁰⁵ TAC will be arguing that competition law may be used to facilitate the market entry of generic competition.

²⁰⁶ In addition, an unsuccessful complaint by Cipla might prevent TAC from launching a similar case at a later stage. Section 67(2) of the Competition Act, 89 of 1998, does not allow for the Competition Tribunal to hear a matter if it is against a firm "that has been a respondent in completed proceedings before the Tribunal under the same or another section of th[e] Act relating substantially to the same conduct." Competition Act 89, § 67(2) (1998).

²⁰⁷ See *The Pharmaceutical Manufacturers' Association v. The President of the Republic of South Africa*, *supra* note 12.

²⁰⁸ Section 1(1)(ix) of the Competition Act defines an excessive price as "a price for a good or service which –
(aa) bears no reasonable relation to the economic value of that good or service; and
(bb) is higher than the value referred to in subparagraph (aa)."

Competition Act 89, § 1(1)(ix).

²⁰⁹ AZT, 3TC and AZT/3TC are such drugs. In addition, it is widely acknowledged that most HIV/AIDS research in the United States is federally sponsored, primarily by the National Institutes of Health. See, e.g. Kaiser Family Foundation, *HIV/AIDS Research: Successes Bring New Challenges—Issue Brief*, 2-3 (June 2000), at <http://www.kff.org/content/2000/1600/research.pdf> (last visited Mar. 28, 2002). See also, Consumer Project on

Third, the “activist” nature of the newly adopted Competition Act provides opportunities that are absent under other regulatory schemes. In short, the legislation is not primarily concerned with the individual parties to a dispute, but rather with the broader social and economic implications of the alleged prohibited conduct.

Fourth, a significant part of the regulatory flexibility afforded by international law, in the form of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),²¹⁰ is dependant upon whether a particular practice is determined to be anti-competitive. Article 31 of TRIPS, which deals with compulsory licensing and arguably offers the greatest potential for increasing access to essential medicines, ordinarily requires that the use of a compulsory license be “predominantly” for the supply of the domestic market. This requirement is waived when the license is issued to remedy an anti-competitive practice.

Finally, and perhaps most important, is the need to revive the public debate about patent abuse and profiteering. TAC is of the opinion that since the collapse of the *Pharmaceutical Manufacturers’ Association* case last year and in the face of price reductions, the campaign against the brand-name pharmaceutical industry has lacked focus. A thorough investigation by the independent Competition Commission into pricing has great potential for achieving these goals.

C. CHALLENGING THE HEALTHCARE INSURANCE INDUSTRY

One of TAC’s key demands for the year is full coverage of treatment for people with HIV/AIDS who utilise the private health sector. At present, the extent of coverage varies considerably, from virtually no coverage for HIV-related treatment to full coverage under the Parliamentary and Provincial Medical Aid Scheme, which provides health care insurance to members of Parliament and the provincial legislatures, judges and the President of South Africa.²¹¹

Based on a report of complaints received by the AIDS Law Project regarding limited benefits offered by one of South Africa’s largest health care insurers, TAC has endorsed a proposal for legal action, and is considering joining the case. At issue is a very broad definition of HIV-related treatment, and the related practice of limited benefits for such treatment. The complaints that will form the basis of the action relate to the cessation of treatment during hospitalisation, with very ill patients being forced to “choose” between carrying the costs of such hospitalisation themselves or else to relocate to a public health facility.

III. CONCLUSION

TAC’s litigation strategies for gaining access to treatment for HIV/AIDS are continually evolving and developing. While litigation is a necessary but in and of itself insufficient form of action, it can effectively be harnessed to win the battle for the hearts and minds of those responsible for providing public health care services, those responsible for determining what public health services will be provided and those who make use of such services. At the core of such strategies lies the recognition that after all the battles have been fought and (hopefully) won, the even more difficult task of implementation has to be taken forward by the very government that will often be at the receiving end of many of these legal battles and public campaigns.

Technology, *Additional notes on government role in the development of HIV/AIDS drugs*, available at <http://www.cptech.org/ip/health/aids/gov-role.html> (last visited Mar. 28, 2002).

²¹⁰ Agreement on Trade-Related Aspects of Intellectual Property Rights, Dec. 14, 1993, RESULTS OF THE URUGUAY ROUND, 33 I.L.M. 81 (1994).

²¹¹ See, e.g., *Aid for AIDS: schemes contracted to AFA*, at http://www.pbm.co.za/AfA_schemes.htm (last visited Mar. 28, 2002).